

# EXHIBIT 1

CONFIDENTIAL

Expert Analysis: Lacey R. Keller

## A. Contents and Figures

1.	Table of Contents	
A.	Contents and Figures .....	2
1.	Table of Contents .....	2
2.	Table of Figures .....	4
B.	Qualifications .....	6
C.	Remuneration .....	9
D.	Scope of Report.....	9
E.	Summary of Opinions.....	9
F.	Materials Reviewed .....	12
G.	Data Included in the Analysis.....	13
H.	Limitations of Analysis .....	13
I.	Overview: Labeler Presence in Summit and Cuyahoga .....	15
J.	Compliance Metric Application.....	16
1.	Twice Trailing Twelve-Month Average (“Double National Average”) .....	17
2.	Three Times Trailing Twelve-Month Average (“Triple National Average”) .....	17
3.	McKesson: 8,000 Rule .....	18
4.	Maximum Monthly, Trailing Six-month Threshold (“Common Sense”) .....	18
5.	Qualitest (Endo): 25%/50% National Average .....	18
6.	Qualitest (Endo): 30,000 Rule .....	19
7.	Mallinckrodt: Rolling Average (Double).....	19
8.	Mallinckrodt: Rolling Average (Triple) .....	20
9.	Purdue.....	20
10.	Actavis (Teva): 125% Order Average.....	21
11.	Teva: Three Standard Deviations.....	21
12.	Multiple Distributors.....	22
K.	Part One: Manufacturer to Prescriber Analysis .....	23
1.	Defendant Access to IQVIA Data.....	27
2.	Results of Compliance Metric Application.....	29
3.	Flagged Prescriber 1: Dr. Clive Sinoff.....	32
4.	Flagged Prescriber 2: Dr. Guang Yang.....	36
5.	Flagged Prescriber 3: Dr. Ronald Celeste .....	40
6.	Flagged Prescriber 4: Dr. James Lundeen .....	43

7.	Flagged Prescriber 5: Dr. Adolph Harper .....	46
8.	Flagged Prescriber 6: Dr. Syed Jawed Akhtar-Zaidi.....	50
9.	Small Labeler Impact.....	53
10.	Baseline Year Analysis.....	56
L.	Part Two: Manufacturer to Pharmacy Analysis .....	58
1.	Results of Compliance Metric Application.....	59
2.	Flagged Pharmacy 1: [REDACTED] .....	63
3.	Flagged Pharmacy 2: [REDACTED] .....	66
4.	Flagged Pharmacy 3: [REDACTED] .....	70
5.	Flagged Pharmacy 4: [REDACTED] .....	73
6.	Flagged Pharmacy 5: [REDACTED] .....	76
7.	Flagged Pharmacy 6: [REDACTED] .....	79
M.	Downstream Customers of Suspicious Orders .....	83
N.	Methodology.....	85
1.	ARCOS Data.....	85
2.	IQVIA Xponent®.....	85
a.	Supplementing the Data - Drug Information .....	87
b.	Supplementing the Data - Prescriber Information .....	88
3.	Chargeback / 867 Data.....	89
a.	Field Mapping .....	91
b.	Summary Chargeback Field Descriptions.....	93
c.	Exclusions.....	93
d.	Data Cleaning and Enrichment .....	94
e.	Calculations.....	97
f.	Anonymous Buyers .....	97
g.	Mismatched Labelers .....	98
4.	Mallinckrodt Peculiar Transactions Data .....	98
O.	Conclusion.....	99
P.	Exhibit 1 – Lacey Keller Resume.....	100
Q.	Exhibit 2 – Results of Manufacturer to Prescriber Analysis Compliance Metric Application .....	101
R.	Exhibit 3 – Results of Manufacturer to Pharmacy Analysis Compliance Metric Application .....	101
S.	Exhibit 4 – Code .....	101



## 2. Table of Figures

Figure 1 Bates Numbers of Defendant Labeler Data .....	12
Figure 2 Number of Dosage Units Flagged by Compliance Metrics, Per Year (IQVIA – Defendant Labelers; 1997-2006, 2008-2017 Summit, Cuyahoga) .....	31
Figure 3 Physician Dosage Units Compared to Per Physician Specialty Average: Sinoff (IQVIA – all labelers; 1997-2006, 2008-2017).....	33
Figure 4 Prescriptions by Labeler Over Time: Sinoff (IQVIA – Defendant Labelers; 1997-2006, 2008-2017) .....	35
Figure 5 Dosage Units by Labeler Over Time: Sinoff (IQVIA – Defendant Labelers; 1997-2006, 2008-2017) .....	35
Figure 6 Physician Dosage Units Compared to Per Physician Specialty Average: Yang (IQVIA – all labelers; 1997-2006, 2008-2017).....	37
Figure 7 Prescriptions by Labeler Over Time: Yang (IQVIA – Defendant Labelers; 1997-2006, 2008-2017) .....	38
Figure 8 Dosage Units by Labeler Over Time: Yang (IQVIA – Defendant Labelers; 1997-2006, 2008-2017) .....	39
Figure 9 Physician Dosage Units Compared to Per Physician Specialty Average: Celeste (IQVIA – all labelers; 1997-2006, 2008-2017).....	40
Figure 10 Prescribing by Labeler: Celeste (IQVIA – all Labelers; 1997-2006, 2008-2017).....	41
Figure 11 Prescriptions by Labeler Over Time: Celeste (IQVIA – Defendant Labelers; 1997-2006, 2008-2017) .....	42
Figure 12 Dosage Units by Labeler Over Time: Celeste (IQVIA – Defendant Labelers; 1997-2006, 2008-2017) .....	42
Figure 13 Physician Dosage Units Compared to Per Physician Specialty Average: Lundeen (IQVIA – all labelers; 1997-2006, 2008-2017).....	44
Figure 14 Prescriptions by Labeler Over Time: Lundeen (IQVIA – Defendant Labelers; 1997-2006, 2008-2017) .....	45
Figure 15 Dosage Units by Labeler Over Time: Lundeen (IQVIA – Defendant Labelers; 1997-2006, 2008-2017) .....	46
Figure 16 Physician Dosage Units Compared to Per Physician Specialty Average: Harper (IQVIA – all labelers; 1997-2006, 2008-2017).....	47
Figure 17 Prescriptions by Labeler Over Time: Harper (IQVIA – Defendant Labelers; 1997-2006, 2008-2017) .....	49
Figure 18 Dosage Units by Labeler Over Time: Harper (IQVIA – Defendant Labelers; 1997-2006, 2008-2017) .....	49
Figure 19 Physician Dosage Units Compared to Per Physician Specialty Average: Akhtar-Zaidi (IQVIA – all labelers; 1997-2006, 2008-2017).....	51
Figure 20 Prescriptions by Labeler Over Time: Akhtar-Zaidi (IQVIA – Defendant Labelers; 1997-2006, 2008-2017).....	52
Figure 21 Dosage Units by Labeler Over Time: Akhtar-Zaidi (IQVIA – Defendant Labelers; 1997-2006, 2008-2017).....	53
Figure 22 Total Prescriptions Over Time Compared to 1997 Prescription Total (IQVIA – Defendant Labelers; 1997-2006, 2008-2017 Summit, Cuyahoga).....	56
Figure 23 Dosage Units by Labeler Over Time: [REDACTED] (ARCOS; 2006 - 2014) .....	64

Figure 24 Dosage Units by Labeler Over Time: [REDACTED] (Chargebacks – Defendant Labelers; Varies Between 1998-2018).....	66
Figure 25 Dosage Units by Labeler Over Time: [REDACTED] (ARCOS; 2006 - 2014).....	68
Figure 26 Dosage Units Per Labeler Over Time: [REDACTED] (Chargebacks – Defendant Labelers; Varies Between 1998-2018).....	69
Figure 27 Dosage Units by Labeler Over Time: [REDACTED] (ARCOS; 2006 - 2014) ...	71
Figure 28 Dosage Units Per Labeler Over Time: [REDACTED] (Chargebacks – Defendant Labelers; Varies Between 1998-2018) .....	72
Figure 29 Dosage Units by Labeler Over Time: [REDACTED] (ARCOS- Defendant Labelers; 2006 - 2014) .....	74
Figure 30 Dosage Units by Labeler Over Time: [REDACTED] (Chargebacks – Defendant Labelers; Varies Between 1998-2018) .....	75
Figure 31 Dosage Units by Labeler Over Time: [REDACTED] (ARCOS; 2006 – 2014) .....	77
Figure 32 Dosage Units by Labeler Over Time: [REDACTED] (Chargebacks – Defendant Labelers; Varies Between 1998-2018) .....	79
Figure 33 Dosage Units by Labeler Over Time: [REDACTED] (ARCOS; 2006 - 2014) .....	81
Figure 34 Dosage Units by Labeler Over Time: [REDACTED] (Chargebacks – Defendant Labelers; Varies Between 1998-2018).....	82

## B. Qualifications

1. I am the Managing Director for Data Mining & Analytics with Gryphon Strategies, Inc. I was hired to create and direct their data mining and analytics division. In my current role, I advise financial and law firms on leveraging data for investments and investigations.
2. Prior to founding Gryphon Strategies' Data Mining & Analytics division, I founded and directed the Research and Analytics Department for the New York State Office of the Attorney General (NYAG) from 2013 to 2017. As a result of my leadership, the NYAG became the first state attorney general's office to hire a data scientist. I grew my staff from one research assistant to seven full-time staff.
3. I have also worked in various research and analytical positions, including the research department of the Service Employees International Union (SEIU) 32BJ, the largest property services union in the country. I was also a researcher for the Global Clearinghouse and a Teaching Assistant at the New School for Social Research. As a consultant, I have been hired by and have provided pro-bono assistance to many state and federal agencies as well as nonprofits on the use of data mining and analytics in investigations.
4. The work I have done throughout my career relates directly to analysis undertaken in this report. For over six years, I have employed a data-driven approach to identifying suspicious, sometimes illegal, conduct. I have developed a specialty in compiling and analyzing disorganized and disparate data. Since 2014, I have been immersed in issues and investigations related to the opioid crisis. This analysis drew upon my unique and specialized skillset that has been developed over a decade of research and analytical experience.
5. I was often tasked with identifying instances of wrongdoing by companies. For example, while at SEIU 32BJ, I reviewed public records for data to identify wrongdoing by cleaning companies and cleaning contractors around the country. For example, through thorough research and documentation, I was able to identify a cleaning company that was creating shell companies to keep a small business cleaning contract at the Walter Reed Medical Center. SEIU 32BJ submitted this information to the General Services Administration. To the best of my knowledge, that company or its subsidiaries/affiliates lost the contract for that site.
6. My primary directive when the NYAG's office hired me was to help the office identify areas for investigation using data. Frequently, I was given a subject area to investigate without having any prior expertise in the area. I would then educate myself through research and talking with subject matter experts to allow me to help them identify new areas of investigation. I often would use public data to assist with these investigations. For instance, I combined publicly available tax assessor, mortgage records, and real estate listings to identify hundreds of land owners potentially out of compliance with the city's 421-a tax benefit program that the NYAG investigated with various settlements with landlords.

7. My work over the past decade has required me to extract, process, clean, merge, and analyze both public and confidential data, which often comes poorly formatted and from disparate locations. From these convoluted datasets, I have identified trends and outliers that have furthered investigations or prosecution.
8. For over four years, I have worked extensively on issues relevant to opioids. While at the NYAG, I developed and managed the Community Overdose Prevention (COP) Program to use data analytics to determine how best to deploy life-saving naloxone across law enforcement officers statewide. Under that program, I oversaw the collection of information related to naloxone disbursements, which jumpstarted tracking opioid overdoses more efficiently throughout the state. I used the data I collected, as well as external datasets, to deepen understanding of opioid usage in New York State. Chief among the datasets I used was the Drug Enforcement Administration (DEA) Automation of Reports and Consolidated Orders System (ARCOS) data. I continue to work with ARCOS data and have now utilized both the publicly available and confidential shipment-level ARCOS data to provide attorneys with granular analysis and support the initiatives and litigation pursued by policymakers and law enforcement.
9. I have written or co-authored numerous reports using my data analysis to advance a variety of investigations into illegal activity, many of which have been covered by national media outlets. For instance, my analysis published in a report issued by the NYAG helped reveal Airbnb's illegal activity in New York City. In addition, while at SEIU 32BJ, I authored two papers about the physical building conditions of New York City public school facilities, the second of which was widely covered by local news and prompted a city council oversight hearing to address the issues raised.
10. In my work, I have frequently received produced data in a format not initially conducive to analysis, such as productions containing PDF versions of spreadsheets or thousands of files of various formats not described in a volume of bates. In a case that settled for hundreds of millions of dollars, I supervised the team that identified and extracted information about shipments from the labeler defendant's production. Because of this analysis, my team and I were able to detect millions of improper shipments made in New York State that were then used by NYAG attorneys in court and ultimately led to the judge ordering the labeler defendant to pay almost \$250 million in damages.
11. My experience also includes processing very disorganized data produced by labeler defendants in various cases for investigations and prosecution. For a wage theft case brought by the NYAG, I was asked to identify instances of an employer "stealing time" from employees. To complete this analysis, I had to extract information from thousands of PDF employee time cards to extrapolate and identify instances of missing time. Based on my analysis, I determined that over \$500,000 in owed money to employees.
12. In my work, I supervise complicated data management and analysis. For an NYAG investigation into posting fake trades in emerging market foreign exchange currency options, I used scripts to extract relevant trade information from two years of instant message, email, and voice communications between brokers. Working with my team, I then compared that relevant

information from postings to the trade confirmations of actual completed trades brokered to determine which trades were real and which were fabricated. This analysis was relied upon to generate a criminal complaint filed by the NYAG. The firms ultimately pled guilty to one count of securities fraud.

13. I am also experienced in working with vast amounts of sensitive information. In developing the interactive dashboard on illegal gun trafficking in New York, the Attorney General's Office obtained the anonymized and the highly confidential firearms tracing data from the Bureau of Alcohol, Tobacco, Firearms and Explosives. My team and I were granted authorization from dozens of police departments to access their firearms trace data on their behalf. I transformed that data into an interactive tool used by New York State law enforcement agencies to identify potential firearms trafficking, based on analytics relevant to firearms trafficking. This data required considerable cleaning and analysis, including geocoding and entity resolution to identify the same firearm purchaser that relied on different aliases, addresses, and other biographical information to avoid detection.
14. I frequently am called upon to analyze very large data. While working on investigations of broadband internet investigations at the NYAG, I collected public speed test data and submissions to office made by the general public about the download speed. This preliminary analysis was the basis for opening an investigation into the practices of the largest broadband providers regarding the internet speeds of its customers. As part of this investigation, I drafted the data request to broadband providers for account and other relevant information that would impact a customer's internet speed. I connected several datasets totaling hundreds of millions of records, including the customer account data (what internet tier they were provisioned), the internet speed test results, as well as information about the modem/router configuration. The results of my analysis and the analysis that I supervised were used in the complaint the Attorney General filed against Time Warner Cable. The case ultimately settled for \$174.2 million.
15. I received the NYAG's Innovation in Law Enforcement Award for my work on gun trafficking and twice received the NYAG's Superior Service Award.
16. I was a member of the 28<sup>th</sup> Class of Coro's Leadership New York and was part of City and State's 40 Under 40 Rising Stars in 2016. I serve on the Standards Review Council for the Multifamily Operating Standards Assessment & Improvement Council (MOSAIC) – a New York Benefit Corporation designed to establish fair and independent operating standards for quality of living within the multifamily housing market.
17. I hold a Master of Economics from the New School and a Bachelor of Business Administration from Washburn University.
18. I have not testified or been deposed in the last four years.
19. I was an invited speaker at the following conferences:

- a. Association of Certified Fraud Examiners (ACFE) Global Fraud Conference (forthcoming: 2019)
- b. NASAA Investment Adviser Training (2017, 2019)
- c. Association of Certified Fraud Examiners (ACFE) Law Enforcement and Government Anti-Fraud Summit (2018)
- d. PLI Hedge Fund and Private Equity Enforcement & Regulatory Developments 2018 (2018)

20. My CV is attached as Exhibit 1.

### C. Remuneration

21. Gryphon is being compensated for its time and expenses. My hourly rate is \$475 per hour. Other Gryphon personnel working on this matter have billing rates of \$275 to \$375 per hour.

### D. Scope of Report

22. This report focuses specifically and exclusively on manufacturers' anti-diversion and suspicious order monitoring programs. Throughout the report, I will refer to labelers and manufacturers interchangeably as the entities that create the drugs analyzed.

23. I have been asked to report the results of applying certain compliance metrics applicable to manufacturers to prescribers.

24. I have been asked to report the results of applying certain compliance metrics applicable to a manufacturer to pharmacies and physicians.

25. I have been asked to trace the orders made by distributors that were deemed peculiar by a manufacturer to the end pharmacy buyer through that manufacturer's chargeback data.

26. I have been asked to report the impact on opioid prescribing in Summit and Cuyahoga County if a small labeler had reported the activity of suspicious prescribers.

### E. Summary of Opinions

27. My findings demonstrate that there were millions of prescriptions and purchases of billions of dosage units and MMEs in Cuyahoga and Summit counties that defendant manufacturers of opioids (called labelers) could have identified as being of unusual size or frequency and deviating from the normal pattern yet were unreported. I found that defendant labelers purchased external data sources (IQVIA) and maintained internal data sources (chargebacks, 867 data, sales data) that provided them with granular information regarding the entity distributing, prescribing, and purchasing their opioid products. All defendant labelers purchased IQVIA Xponent data. All of this information was sufficient to support a Suspicious Order Monitoring (SOM) program identifying problematic distributors, prescribers and pharmacies. In particular, it was and is possible using

standard data-analytic tools to determine from the data that the defendant labelers had in their possession suspicious prescribing and purchasing patterns, and to identify particular physicians and particular pharmacies with problematic prescribing patterns.

28. I found that defendant labelers purchased robust external data sources and maintained internal data sources that provided them with granular information regarding the entity distributing, prescribing, and purchasing their opioid products. This information was sufficient to support a Suspicious Order Monitoring (SOM) program identifying problematic prescribers and pharmacies. Nonetheless, defendant labelers did not implement robust monitoring programs and therefore failed to capture a substantial volume of potentially suspicious transactions.

29. Although all defendant labelers purchased IQVIA Xponent® data, each used it to monitor potential inappropriate prescribing in different ways to differing degrees. Teva and Mallinckrodt, for example, committed to regularly monitor IQVIA Xponent as agreed to with the FDA in their Risk Monitoring Plans (RMP), also known as Risk Minimization Action Plans (RiskMAP).<sup>1</sup> However, the details of how that data analysis would take place and what actions it would lead to was unspecified. To my knowledge only one defendant, Purdue Pharma, used IQVIA in a programmatic or algorithmic way<sup>2</sup>. Implementing Purdue's calculations, however, requires additional data that has not been made available to me.

30. Furthermore, instead of using this data to develop monitoring programs, defendants used it to inform their targeted marketing efforts to prescribers and evaluate drug performance. Similarly, despite the scope and detail of the chargeback data they maintained, defendant labelers did not use that data programmatically or effectively to capture suspicious activity among end buyers.

31. To quantify the prescriptions or transactions that labelers could have readily detected were of unusual size or frequency, I applied a series of compliance metrics to each dataset. Defendant labelers and distributors originally developed all but one of these compliance metrics. Among these metrics were whether the volume prescribed or ordered was over a certain static threshold; whether a buyer significantly increased prescriptions or purchases relevant to their own histories; or how prescriptions or purchases compared to national averages for the same labeler opioid product. I then applied these compliance metrics to physicians and pharmacies to determine what suspicious activity could be detected by labelers. The last metric was derived from labeler defendants' due diligence Standard Operating Procedures documents in which companies expressed concern that pharmacies may be purchasing large quantities of controlled substances from more than one distributor as a means of staying below distributor thresholds. Manufacturers were uniquely positioned to identify end-customers' purchasing patterns and, thus, which customers were using multiple distributors.

32. In Part One of this report, I analyzed the prescribing history of physicians from a labeler's perspective. As previously noted, this analysis relied on IQVIA Xponent® data, which was often purchased by defendant labelers for marketing purposes. In fact, this dataset was produced

---

<sup>1</sup>TEVA\_CHI\_00049296, MNK-T1\_0007204156

<sup>2</sup> PDD1503450011



through discovery to plaintiffs by one of the defendant labelers.<sup>3</sup> By using these compliance metrics, I demonstrated that defendant labelers did not detect millions of prescriptions that could have signaled irregular prescribing patterns. In some cases, labelers even targeted these high-volume prescribers for prescriptions of their product instead of reporting their prescribing patterns as suspect.<sup>4</sup> I found several examples of high opioid-prescribing physicians whose suspicious prescribing could have been evident but, to the best of my knowledge, were not reported by defendant labelers.

33. Part Two of this report analyzed chargeback data. Chargebacks are requests submitted by distributors to labelers to protect distributors from profit loss when drugs are sold to a buyer at less than the distributor paid the labeler for them.<sup>5</sup> Order information – including drug, dosage, package quantity – is contained in the request to demonstrate to the labeler that the opioid product was sold for a lesser value to an end buyer, such as a pharmacy. Because of this system, defendant labelers regularly received chargeback requests from distributors regarding purchases of specific national drug code (NDC) products. This gave the labelers access to information regarding the purchasing patterns of their downstream customers. With this data, I demonstrated that labelers had precise insight into pharmacies in Summit and Cuyahoga that were ordering excessive amounts of their opioid products. Using chargeback data alone, labelers could have detected the suspicious activity of pharmacies, and had they reported them, they would have stopped hundreds of millions of dosage units from being dispensed in Summit and Cuyahoga counties.

34. I was asked by plaintiffs' counsel to include additional analysis that examined what would have happened if a labeler with a comparatively small market share had reported and stopped supplies to suspicious prescribers. I demonstrated that if Janssen – the defendant labeler with the second smallest market share in Summit and Cuyahoga counties – had reported suspicious activity, prescriptions for millions of dosage units could have been stopped in Summit and Cuyahoga counties.

35. The results of my analysis are stark: had the defendant labelers applied similar analytic techniques using their own compliance metrics, that analysis would have identified suspicious orders in Cuyahoga and Summit counties responsible for millions of opioid prescriptions and billions of MMEs, as shown below in Tables 8 through 11. In the aggregate, suspicious orders that defendant labelers could have identified, but apparently did not, were responsible for *more than* half of all opioid prescriptions filled in Summit and Cuyahoga Counties in the periods 1997-2006 and 2008-2017, and for nearly half the MMEs dispensed there in that same period. My analysis also shows that closer analysis of the flagged prescriptions would have confirmed that multiple, identified doctors in Summit and Cuyahoga counties, not limited to those profiled in this report, were engaged in highly suspicious and likely improper prescribing. Similar, closer analysis of flagged pharmacies would have identified specific, identified highly problematic pharmacies. This analysis shows that it is and was possible to identify by name the problematic doctors and

---

<sup>3</sup> ALLERGAN\_MDL\_02485011

<sup>4</sup> MNK-T1\_0001029479

<sup>5</sup> PPLP004397849



pharmacies in Summit and Cuyahoga counties in this period. Using the defendant labelers' own metrics, it was not at all difficult to identify where opioids were being used problematically and where diversion was a concern. Labelers just needed to look.

## F. Materials Reviewed

36. The following documents and data were considered for this report. The staff that worked under my direction had full and complete access to the documents and data produced in this case. They were as follows:

- a. Automation of Reports and Consolidated Orders System (ARCOS) electronic data, received from the DEA and processed by Securities Litigation and Consulting Group, Inc. (SLCG) on or about April 5th, 2019;<sup>6</sup>
- b. IQVIA (formerly Quintiles and IMS Health, Inc.) Xponent® data produced to plaintiffs' counsel through ALLERGAN\_MDL\_02485011 for years 1997-2006, 2008-2017 (there was no data file for 2007);
- c. Chargeback and/or 867 data data from all defendant labelers through thousands of files in different formats (e.g., .csv, .txt, .xlsx, .pdf). The Bates stamps for reviewed documents are shown below by labeler, is shown in the table below;

**Figure 1 Bates Numbers of Defendant Labeler Data**

Labeler Name	Data Source
ENDO	ENDO_DATA-OPIOID_MDL-00000042; ENDO_DATA-OPIOID_MDL-00000044 - ENDO_DATA-OPIOID_MDL-00000084
PAR	PAR_OPIOID_MDL_0001596821 - PAR_OPIOID_MDL_0001596826
QUALITEST	PAR_OPIOID_MDL_0002016651 - PAR_OPIOID_MDL_0002016659; PAR_OPIOID_MDL_0002016661 - PAR_OPIOID_MDL_0002016726
JANSSEN	JAN-MS-03108830 <sup>7</sup>
MALLINCKRODT	MNK-T1_0007965587 - MNK-T1_0007965588
PURDUE	PPLP004418578 - PPLP004422062; PPLP004422064 - PPLP004422150
ACTAVIS	ACQUIRED_ACTAVIS_02001522; ACQUIRED_ACTAVIS_01996164 - ACQUIRED_ACTAVIS_01996173
ALLERGAN	ALLERGAN_MDL_03303052_001; ALLERGAN_MDL_03255576_0002; ALLERGAN_MDL_03255576_0005; ALLERGAN_MDL_03255576_0008; ALLERGAN_MDL_03729472
TEVA	TEVA_MDL_A_02401118; TEVA_MDL_A_02416193 - TEVA_MDL_A_02416204; TEVA_MDL_A_02419960; TEVA_MDL_A_02419961; TEVA_MDL_A_02419963- TEVA_MDL_A_02419969; TEVA_MDL_A_08637273-TEVA_MDL_A_08637277
INSYS <sup>8</sup>	INSYS-MDL-015002410

- d. Peculiar transactions data produced by Mallinckrodt Inc to plaintiffs' counsel through MNK-T1\_0008592627 for years 2003, 2005-2017 (there was no data for 2004);
- e. "National Drug Code Dictionary," Drug Enforcement Administration, November 2018 (current version available at [www.deadiversion.usdoj.gov/arcos/ndc/ndcfile.txt](http://www.deadiversion.usdoj.gov/arcos/ndc/ndcfile.txt));
- f. "NDC Dictionary Instructions," Drug Enforcement Administration, October 2010 (current version available at [www.deadiversion.usdoj.gov/arcos/ndc/readme.txt](http://www.deadiversion.usdoj.gov/arcos/ndc/readme.txt));

<sup>6</sup> McCann, Craig J. *National Prescription Opiate Litigation*. MDL No. 2804. 17-MD-2804. 2019.

<sup>7</sup> Janssen only produced chargeback data for Duragesic and Nucynta for Ohio for years covering 2009 through 2018.

<sup>8</sup> INSYS produced slightly more than 400 lines of data for the entire state of Ohio for 2014 through 2018.

- g. “National Drug Code Directory,” U.S. Food & Drug Administration, January 2018 (current version available at <https://www.fda.gov/drugs/informationondrugs/ucm142438.htm>);
- h. “Opioid Oral Morphine Milligram Equivalent (MME) Conversion Factors,” Centers for Disease Control and Prevention, August 2017 (current version available at [www.cdc.gov/drugoverdose/resources/data.html](http://www.cdc.gov/drugoverdose/resources/data.html));
- i. “NDC: Based On Drug Products in the Medicaid Drug Rebate Program,” Centers for Medicare and Medicaid Services, April 2019 (current available at <https://data.medicaid.gov/Drug-Pricing-and-Payment>);
- j. “Geocoder,” United States Census (current available at <https://geocoding.geo.census.gov/geocoder/>);
- k. “Physician Specialty Codes,” American Medical Association (current available at [http://cdn2.hubspot.net/hub/178504/file-2553042497-pdf/documents/AMA\\_Physician\\_Specialty\\_Codes.pdf?t=1425245957165](http://cdn2.hubspot.net/hub/178504/file-2553042497-pdf/documents/AMA_Physician_Specialty_Codes.pdf?t=1425245957165));
- l. Other documents cited in the text and footnotes below);

## G. Data Included in the Analysis

37. The drugs found in the IQVIA Xponent<sup>®</sup> and chargeback/867 data included in this analysis are limited to the drugs identified in either the ARCOS data or those identified in the expert reports filed by Craig McCann and Meredith Rosenthal. In addition to the drugs they reviewed, I also included Hysingla, labeled by Purdue. Drugs were matched by NDC where possible and on standardized trade name matches. I did not include any buprenorphine or methadone products, even though there is documentation from defendant labelers that they knew that specific drugs in this drug family, namely Butrans and Suboxone, were also often misused and diverted<sup>9</sup>.

38. Although there are other downstream customers, such as hospitals and pain clinics, as in the McCann and Rosenthal reports I only consider prescribers (physicians) and pharmacies (retail, chain) among the analyzed buyers. Including these additional buyers and drugs would have increased the suspicious activity this report identifies.

39. All data is analyzed for the entire time frame available. IQVIA data ranges from 1997 through 2017, with no data produced for 2007, as detailed above. Chargeback data was analyzed for the varied time periods that produced by defendant labelers. ARCOS data was analyzed for years 2006 through 2014.

## H. Limitations of Analysis

40. In drafting this analysis, I had an incomplete set of the defendant labelers’ data. Labeler defendants produced chargeback data for periods shorter than the years that they were manufacturing opioid products. Labeler defendants also had access to and maintained data sources that were more detailed than the chargeback and IQVIA Xponent<sup>®</sup> data that were produced. Produced documentation for some labeler defendants show that supply chain data

---

<sup>9</sup> TEVA\_MDL\_A\_06441627

(such as 867 and 852 data) as well as patient and prescribing data such as IQVIA LRx<sup>®</sup>, were also used in investigations of suspicious prescribers and downstream customers.<sup>10</sup>

41. This analysis does not analyze manufacturer to distributor transactions through ARCOS data, which is the subject of a supplemental report submitted by Craig McCann.

42. The majority of the data produced to me was limited to opioid products; however, suspicious monitoring programs relied on non-controlled substances as a way to benchmark suspicious activity. In fact, several monitoring programs developed by manufactures<sup>11</sup> and distributors<sup>12</sup> relied on the percentage of controlled substances to non-controlled substances as a metric.

43. Additionally, labeler<sup>13</sup> and distributor defendants evaluated the insurance status and method of payment for prescriptions and office visits, in particular the percentage of transactions paid for in cash.<sup>14</sup> I did not have access to such detailed information for this analysis.

44. I implemented the manufacturer and distributor developed compliance metrics as documented, without endorsement. I implemented the metrics using a close reading of the best information available from produced documents and instruction by counsel, providing the most accurate reflection of labeler defendants' monitoring programs as they were represented in their own operating procedures and documentation. If substantially new documents or clarifications were to become available to me, I reserve the right to update the analysis.

45. I had insufficient information from labeler defendants regarding when or whether they reported suspicious activity to the relevant authorities. Furthermore, I have limited knowledge of what action labeler defendants took with prescribers and pharmacies, including (but not limited to) due diligence after they noted suspicious behavior.<sup>15</sup>

46. My opinions are based on my professional experience and training and rely on publicly available data and information and data and documents produced in this litigation, as described below. I continue to review documents and gather information and reserve the right to update my analysis and opinion based on additional documents or data that may become available.

---

<sup>10</sup> Acquired\_Actavis\_00488498, ALLERGAN\_MDL\_01213256, PPLPC023000971890, Crowley-008, TEVA\_MDL\_A\_00339164, TEVA\_MDL\_A\_00339163, Becker deposition (Mallinckrodt), TEVA\_MDL\_A\_00339164

<sup>11</sup> PDD1503450011, ALLERGAN\_MDL\_03535132, ALLERGAN MDL 02146081, TEVA\_MDL\_A\_02476562

<sup>12</sup> MCKMDL00353141, CAH\_MDL\_PRIORPROD\_AG\_0029049, CAH\_MDL\_PRIORPROD\_AG\_0000013, CAH\_MDL\_PRIORPROD\_AG\_0000849

<sup>13</sup> PDD1503450011, Gilles deposition (Mallinckrodt), Tomkiewicz deposition (Actavis/Teva), McGinn deposition (Actavis/Teva)

<sup>14</sup> MCKMDL00353141

<sup>15</sup> Geraci (Purdue 30(b)(6)).

## I. Overview: Labeler Presence in Summit and Cuyahoga

47. The U.S. Food and Drug Administration defines a labeler as, “either a manufacturer, including a repackager or relabeler, or [...] the entity under whose own label or trade name the product will be distributed.”<sup>16</sup> In other words, labelers create brand name and generic drugs that reach the shelves of pharmacies and doctors’ offices. The next step in the distribution chain are the distributors, also often referred to as “wholesalers” by the labelers. I refer these entities as distributors throughout. As stated earlier, this analysis focuses solely on manufacturers’ anti-diversion and suspicious order monitoring programs and does not concern the activities of distributors.

48. Several large labelers dominated the downstream opioid supply in Summit and Cuyahoga from 1997 to 2017. Teva was the largest labeler of generic drugs nationwide, although they had two fentanyl-based brand names on the market in certain years (Fentora and Actiq).<sup>17</sup> Mallinckrodt also manufactured a high percentage of generic drugs but produced a few brand names, like the hydromorphone product Exalgo.<sup>18</sup> Other large labelers like Endo labeled a variety of brand name drugs, while labelers like Purdue became nearly synonymous with a specific brand name (OxyContin). The widespread release of OxyContin in the mid-1990s situated Purdue as a frontrunner among oxycodone labelers.<sup>19,20</sup>

49. The following tables provide a brief overview of which defendant labelers held the largest market shares in Summit and Cuyahoga counties as a backdrop for the detailed analysis of suspicious activity below. The four largest labelers, making up nearly 80% of each county’s market, were Teva, Mallinckrodt., Endo, and Purdue. Johnson & Johnson and INSYS had comparatively small market shares in Summit and Cuyahoga but were nonetheless the fifth and sixth largest labelers (respectively) and sold prominent brand names (Nucynta and Subsys, respectively.)

50. The tables below analyze market shares by three different metrics: prescriptions, dosage units, and morphine milligram equivalents (MMEs). Dosage units<sup>21</sup> were defined as the unit of dosage for a patient – in other words, the number of tablets, milliliters, or patches that may be prescribed or administered to a patient. MMEs allow for comparative analyses of drugs with different molecular bases (i.e., oxycodone, hydrocodone) by assigning each drug a different conversion to morphine.<sup>22</sup> For example, opioid products of the same milligram weight containing

<sup>16</sup>Center for Drug Evaluation and Research. “Drug Approvals and Databases - National Drug Code Directory.” *U S Food and Drug Administration Home Page*, Center for Drug Evaluation and Research, [www.fda.gov/drugs/informationondrugs/ucm142438.htm](http://www.fda.gov/drugs/informationondrugs/ucm142438.htm).

<sup>17</sup> *Tevagenerics.com*, [www.tevagenerics.com/](http://www.tevagenerics.com/).

<sup>18</sup>*Mallinckrodt.com*, <http://www.mallinckrodt.com/medguide/exalgo/>.

<sup>19</sup> “For Healthcare Professionals.” *About OxyContin® (Oxycodone HCL Extended-Release Tablets) CII*, [www.purduepharma.com/healthcare-professionals/products/oxycontin/](http://www.purduepharma.com/healthcare-professionals/products/oxycontin/).

<sup>20</sup> Van Zee, Art. “The Promotion and Marketing of Oxycontin: Commercial Triumph, Public Health Tragedy.” *American Journal of Public Health*, American Public Health Association, Feb. 2009, [www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/).

<sup>21</sup> Office of Regulatory Affairs. “Compliance Policy Guides - CPG Sec 430.100 Unit Dose Labeling for Solid and Liquid Oral Dosage Forms.” *U S Food and Drug Administration Home Page*, Office of Regulatory Affairs, [www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074377.htm](http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074377.htm).

<sup>22</sup> “Opioid Morphine EQ Conversion Factors August 2017.” *CMS.gov Centers for Medicare & Medicaid Services*, 3 Apr. 2019, [www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/](http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/).

hydromorphone (Exalgo) will be four times more potent than drugs containing hydrocodone (Norco, Vicodin).

**Table 1 Labeler Market Shares in Summit County**  
(IQVIA – All Labelers; 1997-2006, 2008-2017)

*Table sorted by total prescriptions.*

Labeler Name (Parent)	Total Prescriptions	% of County Prescriptions	Total Dosage Units	% of County Dosage Units	Total MMEs	% of County MMEs
Mallinckrodt	2,366,237	33.2	121,097,857	31.8	1,048,055,586	24.3
Teva	2,080,501	29.2	102,813,194	27	914,086,141	21.2
Endo	1,118,451	15.7	61,951,952	16.3	713,074,462	16.5
Purdue	235,618	3.3	14,659,133	3.8	738,600,695	17.1
Johnson & Johnson	62,199	0.9	568,006	0.1	3,413,288	0.1
INSYS	5	<0.1	190	<0.1	3,806	<0.1
Other Labelers	1,254,166	17.6	79,954,454	21	895,266,239	20.8
<b>Total</b>	<b>7,117,177</b>	<b>100</b>	<b>381,044,786</b>	<b>100</b>	<b>4,312,500,2167</b>	<b>100</b>

**Table 2 Labeler Market Shares in Cuyahoga County**  
(IQVIA – All Labelers; 1997-2006, 2008-2017)

*Table sorted by total prescriptions.*

Labeler Name (Parent)	Total Prescriptions	% of County Prescriptions	Total Dosage Units	% of County Dosage Units	Total MMEs	% of County MMEs
Mallinckrodt	5,412,473	31.1	286,004,826	29.9	2,438,694,082	22.4
Teva	5,311,338	30.5	266,513,848	27.9	2,419,164,714	22.2
Endo	2,814,279	16.2	156,699,833	16.4	1,725,571,501	15.8
Purdue	642,439	3.7	42,382,962	4.4	2,045,346,306	18.8
Johnson & Johnson	117,832	0.7	1,105,815	0.1	6,484,694	0.1
INSYS	703	<0.1	59,158	<0.1	22,716,67	<0.1
Other Labelers	3,088,173	17.8	203,227,901	21.3	2,265,829,792	20.8
<b>Total</b>	<b>17,387,237</b>	<b>100</b>	<b>955,994,343</b>	<b>100</b>	<b>10,901,091,089</b>	<b>100</b>

## J. Compliance Metric Application

51. I was instructed by counsel to apply metrics derived and used by any manufacturer or distributor and to also apply metrics applied in enforcement actions (i.e., McKesson, Masters) to all datasets to detect prescribing and purchasing patterns of unusual size, frequency, and pattern.<sup>23</sup>

52. While to the best of my knowledge, no manufacturer applied any compliance metric to IQVIA data, the application of these metrics would have allowed defendant labelers to identify unusually high volume prescribers. I was instructed by counsel that these prescribers are more likely be suspicious prescribers, practicing in violation of state and federal requirements. See, e.g., ORC 4731.052.

53. Every month, metrics were re-applied so that an entity (i.e., physician, pharmacy) that was flagged in the previous month was not flagged by default in the following month. This provided a lower estimate of the number of physicians or pharmacies that were flagged by each compliance metric and gave the manufacturer credit as if diligence was performed on that entity in that month.<sup>24</sup> For many, if not all of the labeler defendants, that may be an unearned credit. I can, and

<sup>23</sup> 21 CFR 1301.74(b)

<sup>24</sup> I am aware that the McCann report assumed that the distributor did not perform any diligence. That approach is equally reasonable.

reserve the right to, supplement this report to provide an analysis of suspicious activity that could have been identified by manufacturers in the absence of diligent investigations of suspicious prescribers and pharmacies.

54. Prescribers were grouped by specialty to ensure that doctors with higher baseline opioid prescribing rates were not compared to characteristically low volume opioid prescribers. Similarly, pharmacies were grouped into chain and retail pharmacy cohorts. The table below provide an overview of what compliance metrics were applied to distinct business activities. The enumerated list that follows describes each compliance metric in detail.

**Table 3 Compliance Metric Application by Purchaser Type**

Metric	Distributor	Physician	Pharmacy
Double National Average	X	X	X
Triple National Average	X	X	X
McKesson: 8,000 Rule	X	X	X
Masters: Common Sense	X	X	X
Qualitest (Endo): 25%/50% National Average	X		X
Qualitest (Endo): 30,000 Rule	X		X
Mallinckrodt: Rolling Average (Double)	X		X
Mallinckrodt: Rolling Average (Triple)	X		X
Purdue			
Actavis (Teva): 125% Order Average	X		X
Teva: 3 SD Above Six Month Mean	X		X
Multiple Distributor	X		X

1. Twice Trailing Twelve-Month Average (“Double National Average”)<sup>25</sup>

55. Within a calendar month (i.e., May 2007), if volume of transactions (prescriptions, chargebacks), dosage units, or MMEs either prescribed or purchased were more than twice the average for the cohort (i.e., other chain pharmacies, retail pharmacies, or physicians) nationally within the same month, the entity and their transactions were flagged. This metric was applied to all physicians and pharmacies. This metric was applied to IQVIA and chargeback data. I expand on the McCann analysis by applying this metric not only to dosage units but also transactions (prescriptions, chargebacks) and MMEs.

2. Three Times Trailing Twelve-Month Average (“Triple National Average”)<sup>26</sup>

56. Within a calendar month (i.e., May 2007), if volume of transactions (prescriptions, chargebacks), dosage units, or MMEs either prescribed or purchased were more than triple the average nationally to the cohort (i.e., other chain pharmacies, retail pharmacies, or physicians) within the same month, the entity was flagged. This metric was applied to IQVIA and chargeback data. I expand on the McCann analysis by applying this metric not only to dosage units but also transactions (prescriptions, chargebacks) and MMEs.

<sup>25</sup> McCann, Craig J. *National Prescription Opiate Litigation*. MDL No. 2804. 17-MD-2804. 2019.

<sup>26</sup> McCann, Craig J. *National Prescription Opiate Litigation*. MDL No. 2804. 17-MD-2804. 2019.



3. McKesson: 8,000 Rule<sup>27</sup>

57. An entity that prescribed or purchased more than 8,000 dosage units of oxycodone or hydrocodone within a calendar month was flagged, according to McKesson's "Lifestyle Drug Monitoring Program." The parameters for McKesson's Lifestyle Drug Monitoring Program were described as "McKesson will investigate customer activity when sales of a given generic base ingredient exceed a predefined dosage unit threshold within a calendar [sic] month... The same dosage threshold will be used for all classes of customers." McKesson only tracked four drug types, two of which were non-opioids. In IQVIA data, prescribers who wrote more than 8,000 dosage units of hydrocodone or oxycodone in a month were flagged, as were buyers who submitted more than 8,000 dosage units' worth of chargebacks for oxycodone or hydrocodone. This metric was applied to IQVIA and chargeback data.

4. Maximum Monthly, Trailing Six-month Threshold ("Common Sense")<sup>28</sup>

58. Entities triggered this metric if their prescriptions or orders within a rolling 30-day period were in excess of their maximum dosage units or frequency of transactions in any of the preceding six months. Any orders within a month that deviated from the previous six-month trend were flagged. The methodology for this metric comes from *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017).

59. In order to meet the statutory requirements to monitor transactions of "unusual size, frequency, or pattern," the "Maximum Monthly, Trailing Six-month Threshold" rule was outlined as the following:

- i. ...that order—combined with other orders placed in the same 30-day period—requested more doses of a controlled medication than the pharmacy had requested in any of the previous six calendar months; (b) the pharmacy ordered a controlled medication more frequently in a 30-day period than it had in any of the previous six calendar months;

60. Any order that was shipped to a customer after it had been established that the customer had exceeded the six-month threshold was unlawful. This metric was applied to all distributors, physicians, and pharmacies. Each entity was held only to its own ordering or prescribing history. This metric was applied to IQVIA and chargeback data.

5. Qualitest (Endo): 25%/50% National Average<sup>29</sup>

61. This metric captured buyers whose purchases for the month were 25% of the national average for a single drug code for retail pharmacies or 50% of the national average for a single drug code for chain pharmacies: "The maximum boundary for a pharmacy is 25% of the national average for the number of prescriptions filled monthly...Chains typically receive 50% of national average due to the limited number of brands on the pharmacy shelves and the Qualitest primary position. For a customer to receive 100% of the national average, Qualitest would need to be the only brand stocked and the only supplier of the product."

---

<sup>27</sup> MCKMDL00355041

<sup>28</sup> McCann, Craig J. *National Prescription Opiate Litigation*. MDL No. 2804. 17-MD-2804. 2019.

<sup>29</sup> Qualitest did not use chargeback data until after their March 2013 meeting with DEA, PAR\_OPIOID\_MDL\_0000021256, T. Norton Tr. 71:12-73:5, E. Brantley 472:9-11

62. The only data source to which this metric could be applied was ARCOS and it was only applied to the transaction data of Qualitest because the metric's 25%/50% threshold logic was based on Qualitest market share, which Qualitest identified as smaller than other labelers.<sup>30</sup> According to internal Qualitest communication, "The allowable averages are based on IMS and DEA ARCOS data." IMS data that included filling pharmacy information was not made available by labeler defendants for this analysis, but national averages were calculated using confidential ARCOS data covering the years 2006-2014. National averages were calculated for all drugs and all labelers as necessary for implementation, but flagged data was limited only to Qualitest NDC. Qualitest further notes that, "One way we fulfill this requirement is by reviewing chargeback data, which gives us visibility into the quantities secondary customers (usually pharmacies) are purchasing of our NDC numbers from our direct customers. This allows us to identify potentially suspicious activity and alert our direct customers and obtain due diligence information from them."<sup>31</sup> As noted above, this metric was applied only to Qualitest's ARCOS data.

6. Qualitest (Endo): 30,000 Rule<sup>32</sup>

63. This metric was applied by Qualitest to capture any buyer within one calendar month that purchased more than 30,000 dosage units of hydrocodone purchases. This metric was applied to the chargeback data of all labeler defendants. In internal Qualitest communications, a threshold of 30,000 monthly units is specified as an output of an improved chargeback monitoring system, "Output. A list of all DEA registrants that purchased a minimum of 30,000 dosage units of any size or strength of Hydrocodone in the months identified, including a breakdown by month. It must also list the direct customer (wholesaler) the hydrocodone was purchased from. (There may be multiple wholesalers for one secondary customer.) Another option is to show all registrants that purchased 180,000 dosage units over the 6 month time frame with a breakdown by month."<sup>33</sup> This metric was applied only to the hydrocodone transactions for labeler defendants' chargeback data.

7. [REDACTED]<sup>34</sup>

64. This metric was applied by Mallinckrodt to identify buyers whose purchases within a [REDACTED] period [REDACTED]. Average purchases were evaluated both for order quantity (understood to be dosage units and MMEs) and order frequency (count of transactions submitted by a customer).<sup>35</sup> Customers were held only to [REDACTED]  
[REDACTED]  
[REDACTED]. Customers were not evaluated by this SOMS program in the first six months of their relationship with Mallinckrodt. The rule also stipulated that the date be adjusted to always include [REDACTED]. However, chargeback data was not provided in a format that allowed for [REDACTED]  
[REDACTED]. A rolling average would potentially capture more problematic purchases for customers that

<sup>30</sup> PAR\_OPIOID\_MDL\_0000021256

<sup>31</sup> PAR\_OPIOID\_MDL\_0000000867

<sup>32</sup> PAR\_OPIOID\_MDL\_0000000867

<sup>33</sup> PAR\_OPIOID\_MDL\_0000000868

<sup>34</sup> MNK-T1\_0007476284

<sup>35</sup> MNK-T1\_0007476290, MNK-T1\_0007476296



have split large orders between months, potentially to avoid detection. This metric was applied to the chargeback data of all defendants.

8. Mallinckrodt: [REDACTED]<sup>36</sup>

65. According to communications with plaintiffs' counsel, Mallinckrodt at some points edited their SOMS program to capture buyers whose purchases within a [REDACTED] period were [REDACTED], rather than the [REDACTED], as specified in provided documents. As with the [REDACTED] metric, the threshold worked off an adjusted date that always included [REDACTED]. However, chargeback data was not provided in a format that allowed for [REDACTED]. A rolling average would potentially capture more problematic purchases for customers that have split large orders between months, potentially to avoid detection, as I have seen occur in the data. This metric was applied to the chargeback data of all defendants.

9. Purdue<sup>37</sup>

66. Purdue's "Downstream" customer SOP<sup>38</sup> (dated of Jan 2018) mentioned using chargeback data. However, it did not specify any thresholds, measures, rules, or algorithms used to analyzed chargebacks. The most specific information on the method of identifying suspicious downstream customers was: "Orders of Covered Products that significantly exceed monthly dispensing averages based on IMS data and/or the distributor's monthly order averages from like customers."<sup>39</sup> None of the following crucial definitions was included in the Standard Operating Procedures:

- a. The definition of "significantly"
- b. The duration of the period over which "monthly dispensing averages" would be calculated
- c. The definition of "like customers"
- d. Under what circumstances IMS data would be used vs. distributor data
- e. Definition of what distributor data would be used in place of IMS
- f. Whether IMS data would be used to calculate per-downstream-customer average dispensing, or national averages for customers in general

67. Purdue's direct customer SOPs (draft dated 2015 according to counsel,<sup>40</sup> effective versions dated Sep. 25 2017<sup>41</sup>) did not specify specific thresholds, rules, or algorithms. Standard Operating Procedure 000017 defined Purdue's SOM tool/program as: "A cloud based IT program that uses an algorithm and custom rules/Thresholds to identify and pend Orders of Interest."<sup>42</sup> No further information about the algorithm was provided. The "thresholds" were discussed, but SOM

---

<sup>36</sup> MNK-T1\_0007476284

<sup>37</sup> Purdue's metric, to the extent it exists, was not clear enough to apply to this analysis. The rules for lifting flags were based on arbitrary customer-by-customer "multipliers", plus rules about the days' supply were either 8 days (total), the agreed-upon baseline in a contract plus an additional 7 days, or the agreed-upon baseline plus an additional 30 days –fall depending on the kind of contract or agreement in place at the time between Purdue and their customer.

<sup>38</sup> PPLPC023000971890

<sup>39</sup> PPLPC023000971893

<sup>40</sup> PPLPC032000374808

<sup>41</sup> PPLP004393084, PPLP004368540

<sup>42</sup> PPLP004368541

000018 and the 2015 draft revealed that these customer thresholds were not determined programmatically. Instead, they were determined on a per customer basis, or “based in part on the information provided by the customer.” It was further stated that they “will be routinely adjusted at least annually based on updated national dispensing data, and customer information provided on annual review questionnaire... at any time throughout the year, the Thresholds will be adjusted accordingly.”<sup>43</sup> Because of its lack of precision, I did not apply this metric.

10. Actavis (Teva): 125% Order Average<sup>44</sup>

68. Unlike all other metrics, this Actavis-applied metric operated at the order level. It was calculated to flag any buyer that placed a single order that was 125% of their previous six-month average per order of a specific NDC. This metric is unusual among others used by the labeler defendants in that it does not look at the aggregate volume for a customer. As explained in internal communications in April 2008, “The DEA suspicious order report is not all that it’s thought to be. It looks at order quantities and compares them against a customer’s monthly usage. A customer can order three times a day or then times a week. Unless a customer places a large quantity (above their average) all at once, it won’t necessarily come up as suspicious. This is one of several flaws with this report.”<sup>45</sup> This metric was applied to the chargeback data of all defendants.

11. Teva: Three Standard Deviations<sup>46</sup>

69. Teva’s SOMS system (referred to as SORDS II) was in effect from approximately 2012 to 2015, when it was replaced by a system called DefOps.<sup>47</sup> According to the Buzzeo/Cegedim compliance report, orders (by NDC) that were more than three standard deviations above the customer’s monthly mean were flagged by Teva: “Standard deviations are calculated for each product on a monthly and quarterly basis. Any order that is in excess of three standard deviations above the mean is ‘pending’ for further investigation.”<sup>48</sup> The monthly mean was “refreshed” periodically: “recalculated... previously agreed upon six months.”<sup>49</sup> I understood this to mean that the mean and standard deviation were calculated approximately twice per year, using the most recent six months of data. Orders were only evaluated based on volume, not frequency or pattern of orders.<sup>50</sup> Buzzeo notes that, “orders are ‘normalized’ for package size,”<sup>51</sup> which I understood to mean that dosage units were used as the measure for this metric. Mean and standard deviation were calculated among the monthly totals per NDC per customer, grouping within drug types, according to my understanding of Buzzeo’s use of “product family” and “individual”: “The system measures orders by product family and focuses on individual DEA registration number.”<sup>52</sup> This metric was applied to the chargeback data of all defendants.

---

<sup>43</sup> PPLP004393089

<sup>44</sup> Allergan\_MDL\_02081243, Allergan\_MDL\_02128514

<sup>45</sup> Allergan\_MDL\_03411273

<sup>46</sup> TEVA\_MDL\_A\_01060005

<sup>47</sup> TEVA\_MDL\_A\_01060005, p 265 of McGinn Deposition

<sup>48</sup> TEVA\_MDL\_A\_01060008

<sup>49</sup> TEVA\_MDL\_A\_01060009

<sup>50</sup> TEVA\_MDL\_A\_01060009

<sup>51</sup> TEVA\_MDL\_A\_01060008

<sup>52</sup> TEVA\_MDL\_A\_01060008

70. Teva's more recent SOMS program, known as DefOps, went into effect around 2015. Teva has referred to this system as an "algorithm," but that term does not refer to the methodology for setting suspicious order limits. Suspicious order thresholds (called Upper Control Limits or UCLs by Teva), are based on two standard deviations above the mean<sup>53</sup> per drug, but the program was designed to allow "ability to adjust parameters by customer."<sup>54</sup> Customer order quantity is calculated in milligrams.<sup>55</sup> Available documents do not specify the number of periods over which the mean and standard deviation are calculated for monthly and quarterly averages. Documents are contradictory on whether the UCLs are set per customer<sup>56</sup>, later referencing the UCLs listed in the DEA Drug Class Controls table<sup>57</sup>. The fields of that table are shown in the document and do not contain customer ID information—only customer type class (e.g., "wholesaler") and customer size class (e.g. Extra Small, Medium). My understanding based on documents and communication with counsel is that customer limits start from a common baseline and are individually manipulated per customer. Teva's DefOps SOMS was not replicated here because it is not programmatic, and documentation does not contain sufficient information to implement the DefOps rules as if they were.

## 12. Multiple Distributors

71. When distributors set thresholds for triggering suspicious orders, buyers could have purchased opioids from multiple distributors to evade compliance thresholds. For example, if a buyer wanted to purchase a greater quantity of a drug than McKesson allowed within a specific time, the buyer may have obtained the same drug from another distributor in addition to its standing purchases from McKesson. Doing so would allow the buyer to obtain the desired quantity of the drug while remaining within distributor limitations. Buyers were flagged when they purchased the same drug formulation (drug family and dosage strength) from two or more distributors within one calendar month. Buyers were not limited to a cohort or percentile of purchasing for this metric, which was applied to all pharmacies. Manufacturers also use this approach, to differing degrees, to detect downstream customers that were ordering their products through more than one distributor to evade distributors' SOMs programs. Actavis specifically mentioned chargeback data as a useful tool for doing so,<sup>58</sup> "Compliance will review Charge-back data for key products with the objective of ensuring that pharmacy level customers are not purchasing excessive quantities of controlled drug products from multiple supplier sources." Purdue similarly discussed using its chargeback data to identify downstream customers using multiple distributors: "Review other wholesaler/distributor 867 and/or Chargeback Data to determine the amount of Covered Product the Downstream Customer is obtaining from different wholesalers/distributors."<sup>59</sup> This metric was applied to chargeback data.

---

<sup>53</sup> TEVA\_MDL\_A\_03479116

<sup>54</sup> TEVA\_MDL\_A\_02476562

<sup>55</sup> TEVA\_MDL\_A\_03479124

<sup>56</sup> TEVA\_MDL\_A\_03479124

<sup>57</sup> TEVA\_MDL\_A\_03479120

<sup>58</sup> TEVA\_MDL\_A\_01037233

<sup>59</sup> PPLPC023000971894

## K. Part One: Manufacturer to Prescriber Analysis

72. This section examines patterns of transaction between labelers and prescribers. IQVIA describes the key prescription information offerings of Xponent® data as: “A suite of sub-national reporting providing granular prescription performance perfectly aligned to help manage customer operations, sales targeting, and representative incentive compensation.”<sup>60</sup> IQVIA is not reported through a government agency but is proprietary and available for purchase by pharmaceutical companies. Because IQVIA is survey data, figures are representative samples of prescription information per physician as reported by dispensing pharmacies.<sup>61</sup> Nonetheless, according to National Sales Perspectives from November 2017, IQVIA data covered 93% of all prescriptions filled by retail pharmacies.<sup>62</sup> Due to rounding differences in such high volume data, percentages in IQVIA-based table totals will differ, depending on the metrics being displayed and what level of granularity is being used. Rather than adjusting numbers, I have preserved the raw form of the data in as exact of a format as possible, while rounding to whole numbers.

73. Among the dozens of opioid-prescribing medical specialties, some prescribed opioids more often than others. The American Medical Association identified eight specialties as more likely opioid prescribers: primary care physicians (general practitioner/family medicine/internists), dentists, orthopedic surgeons, ear/nose/throat doctors, emergency care physicians, obstetricians/gynecologists, and anesthesiologists.<sup>63</sup> In 2012, almost half of all opioids dispensed by pharmacies were prescriptions written by primary care physicians, according to a study described in the American Journal for Preventative Medicine.<sup>64</sup> IQVIA data reflected the same trend, as general/family practitioners wrote more opioid prescriptions than any other specialty.

74. However, just as there were specialties more inclined to write opioid prescriptions, there were specialties with less of a need – such as pediatricians and nutritionists – that were still found as opioid prescribers in the IQVIA data. Furthermore, certain specialties with a small number of practicing physicians accounted for a disproportionately high number of opioid prescriptions. For example, pain management specialists were less than 1% of the number of opioid-prescribing physicians nationwide but held a 4% share of the market in terms of prescriptions and had the third highest percentage of dosage units (5.4%), as shown in the following table. Similarly, physical rehabilitation specialists accounted for 1% of opioid-prescribing physicians but prescribed 4% of dosage units and 6.3% of MMEs.

75. The table below ranks each physician specialty on a national level by the number or opioid prescriptions written per specialty. Specialties were grouped according to the methodology provided at the end of this report. The table that follows displays the percent of prescriptions of

<sup>60</sup> “Prescription Information.” IQVIA, [www.iqvia.com/locations/united-states/commercial-operations/essential-information/prescription-information](http://www.iqvia.com/locations/united-states/commercial-operations/essential-information/prescription-information).

<sup>61</sup> IMS Health & Quintiles, “National Sales Perspectives & National Prescription Audit Overview.” IQVIA: 2017.

<sup>62</sup> IMS Health & Quintiles, “National Sales Perspectives & National Prescription Audit Overview.” IQVIA: 2017.

<sup>63</sup> American Medical Association. April 6, 2011. Characteristics of Opioid Prescriptions in 2009. JAMA Vol. 305, No. 13. <<https://jamanetwork.com/journals/jama/fullarticle/896134>> .

<sup>64</sup> Levy, Benjamin et al. Trends in Opioid Analgesic—Prescribing Rates by Specialty, U.S., 2007-2012. *Am J Prev Med*. 2015 September: 49(3):409-413.

all drugs for which each specialty was responsible to contextualize the patterns observed for opioid prescribers. Note that this list is for reference and does not offer per capita calculations.

**Table 4 Nationwide Opioid-Prescribing by Specialty**  
**(IQVIA – All Labelers; 1997-2006, 2008-2017)**

Table sorted by the total number of physicians.

Physician Specialty	Total Physicians	% of National Physicians	Total Prescriptions	% of National Prescriptions	Total Dosage Units	% of National Dosage Units	MMEs	% of National MMEs
Family/General	641,392	34.8	1,473,260,658	43.3	97,968,415,862	50.7	1,245,839,647,794	52
Surgery	137,053	7.4	509,157,437	15	24,516,101,201	12.7	179,039,776,929	7.5
Dentistry	244,603	13.3	278,269,117	8.2	5,197,260,949	2.7	31,948,492,312	1.3
Emergency/Critical	70,954	3.8	215,986,951	6.4	5,422,099,163	2.8	43,245,510,307	1.8
Pain Medicine	6,717	0.4	117,326,352	3.5	10,523,280,054	5.4	204,743,473,240	8.5
Unknown	65,169	3.5	111,661,420	3.3	4,957,581,111	2.6	45,048,122,898	1.9
Physical/Occupational Rehabilitation	15,980	0.9	98,246,790	2.9	8,199,178,000	4.2	151,700,016,506	6.3
Obstetrics/Gynecology	67,518	3.7	95,538,216	2.8	2,863,384,982	1.5	22,838,616,952	1
Neurology	33,978	1.8	87,268,037	2.6	5,736,809,496	3	78,381,638,248	3.3
Anesthesiology	45,324	2.5	85,984,338	2.5	7,515,128,725	3.9	149,228,727,513	6.2
Oncology	28,056	1.5	55,469,938	1.6	4,835,289,790	2.5	69,601,478,287	2.9
Rheumatology	7,464	0.4	40,373,460	1.2	3,668,279,212	1.9	42,342,630,306	1.8
Urology	16,630	0.9	35,763,479	1.1	1,104,419,948	0.6	8,432,709,850	0.4
Other Specialty	49,622	2.7	29,920,875	0.9	1,086,436,931	0.6	9,359,919,411	0.4
Orthopedics	5,909	0.3	22,950,038	0.7	1,138,274,378	0.6	10,702,093,931	0.4
Cardiology	38,883	2.1	16,454,316	0.5	974,577,201	0.5	9,693,762,731	0.4
Pediatrics	72,923	4.0	14,852,664	0.4	889,950,381	0.5	6,455,052,595	0.3
Psychiatry	64,318	3.5	13,969,170	0.4	1,018,226,414	0.5	18,392,236,071	0.8
Geriatrics	6,068	0.3	13,090,020	0.4	990,495,978	0.5	12,473,605,236	0.5
Gastroenterology/	20,036	1.1	12,106,265	0.4	762,618,139	0.4	7,537,825,532	0.3
Proctology								
Nephrology	12,622	0.7	10,435,636	0.3	654,588,386	0.3	6,655,809,107	0.3
Administrative/	7,324	0.4	9,788,767	0.3	559,338,339	0.3	6,547,927,918	0.3
Management								
Pulmonology	9,084	0.5	9,439,734	0.3	652,499,724	0.3	7,285,489,500	0.3
Ophthalmology	27,744	1.5	8,268,862	0.2	217,452,156	0.1	2,179,071,447	0.1
Pathology/Epidemiology	20,342	1.1	7,716,878	0.2	531,111,562	0.3	7,862,312,412	0.3
Endocrinology	11,103	0.6	6,360,129	0.2	394,775,486	0.2	4,370,034,671	0.2
Dermatology	16,817	0.9	5,766,530	0.2	151,619,350	0.1	1,185,439,948	0
Hematology/								
Phlebotomy	2,829	0.2	4,375,299	0.1	334,173,935	0.2	5,271,961,551	0.2
Radiology	33,725	1.8	3,081,028	0.1	147,468,823	0.1	2,138,394,987	0.1
Allergy/Immunology	6,335	0.3	1,621,742	0	98,899,214	0.1	1,127,799,349	0
Veterinary	50,316	2.7	1,241,801	0	45,482,284	0	473,676,328	0
Addiction	525	0.0	1,169,738	0	83,916,810	0	1,825,384,739	0.1
Aerospace/Hyperbaric/Nuclear	2,215	0.1	941,225	0	47,134,223	0	610,781,963	0
Sleep Medicine	1,017	0.1	582,265	0	36,740,744	0	415,062,272	0
Pharmacology	1,394	0.1	248,765	0	19,124,159	0	341,644,077	0
Medical Toxicology	331	0.0	227,530	0	4,842,661	0	33,865,684	0
Hepatology	461	0.0	207,552	0	12,890,830	0	143,088,865	0
Nutrition	167	0.0	108,960	0	7,372,255	0	120,647,917	0
Genetics	701	0.0	84,693	0	4,647,056	0	55,057,518	0
Research	64	0.0	4,854	0	343,978	0	5,190,489	0



**Table 5 Nationwide Average Annual Opioid-Prescribing Per Physician by Specialty (IQVIA – All Labelers; 1997-2006, 2008-2017)**

*Table sorted by annual average prescriptions per physician.*

Physician Specialty	Total Physicians	Average Annual Prescriptions Per Physician	Average Annual Dosage Units Per Physician	Average Annual MMEs Per Physician
Pain Medicine	6,717	832	74,603	1,451,495
Physical/Occupational Rehabilitation	15,980	293	24,433	452,053
Rheumatology	7,464	258	23,403	270,139
Orthopedics	5,909	185	9,173	86,245
Surgery	137,053	177	8,518	62,207
Emergency/Critical	70,954	145	3,639	29,023
Neurology	33,978	122	8,040	109,849
Family/General	641,392	109	7,273	92,495
Addiction	525	106	7,612	165,568
Geriatrics	6,068	103	7,773	97,887
Urology	16,630	102	3,162	24,147
Oncology	28,056	94	8,207	118,134
Anesthesiology	45,324	90	7,896	156,785
Unknown	65,169	82	3,623	32,917
Hematology/Phlebotomy	2,829	74	5,625	88,740
Obstetrics/Gynecology	67,518	67	2,019	16,108
Administrative/Management	7,324	64	3,637	42,573
Dentistry	244,603	54	1,012	6,220
Pulmonology	9,084	49	3,420	38,191
Nephrology	12,622	39	2,470	25,110
Medical Toxicology	331	33	697	4,872
Nutrition	167	31	2,102	34,402
Gastroenterology/Proctology	20,036	29	1,812	17,915
Other Specialty	49,622	29	1,043	8,982
Endocrinology	11,103	27	1,693	18,742
Sleep Medicine	1,017	27	1,720	19,434
Hepatology	461	21	1,332	14,780
Aerospace/Hyperbaric/Nuclear	2,215	20	1,013	13,131
Cardiology	38,883	20	1,194	11,872
Pathology/Epidemiology	20,342	18	1,243	18,405
Dermatology	16,817	16	429	3,357
Ophthalmology	27,744	14	373	3,740
Allergy/Immunology	6,335	12	743	8,477
Pediatrics	72,923	10	581	4,215
Psychiatry	64,318	10	754	13,617
Pharmacology	1,394	8	653	11,671
Genetics	701	6	316	3,740
Radiology	33,725	4	208	3,019
Research	64	4	256	3,862
Veterinary	50,316	1	43	448

1. Defendant Access to IQVIA Data

76. I was informed that defendant labelers used IQVIA data to identify their best prescribers – yet many of these methods could have instead been applied to detect suspicious prescribers. To illustrate this point, I highlight Endo’s 2009 incentive compensation plan for Opana ER, which stated:

- a. “Rx credit is awarded for all physician TRxs (IMS Xponent® normalized prescription data) generated in a representative’s zip code-defined ... All sales performance is based on IMX Xponent® normalized prescription data. Payment dates are contingent upon the timely arrival of Xponent® data to Endo for final IC Plan calculations at the close of the trimester.”<sup>65</sup>

77. In a 2012 document entitled “Managed Market Summit,” Janssen acknowledges the receipt of numerous data sources, including inventory (852), sales (867), returns (180), and chargeback data (844/849), which allowed them to “un-blind and unblock” the inventory and shipments to chain pharmacies and stores (they also note the data was not available before 2011).<sup>66</sup> In later slides, they highlight some of the details they could obtain from the data, including down to the NDC and store. “For the first time, our sales reps know which pharmacies have purchased, and which high decile pharmacies have not purchased our products.”<sup>67</sup> In a separate document, Janssen requests “updates of hot spot markets prescribers writing the higher strengths so that I can provide that data to the JOM Planners and Wholesale Buyers. CSOS will certainly accelerate speed to market with shipment”<sup>68</sup>

78. Each of the defendant labelers had access to IQVIA Xponent® data. Consequently, the compliance metrics were applied to prescriptions of all labeler products, as the labeler defendants saw prescriptions of more than just their own products via the IQVIA data. I am further aware that labelers had access to point of sale (e.g., 867, IntegriChain) data that could have been leveraged for this purpose.<sup>69</sup>

79. Documents produced by Purdue reveal that Purdue was programmatically evaluating suspicious prescribers on a monthly basis using Xponent® data beginning in 2002, in cooperation between their sales team and general counsel. Prescribers were evaluated based on a few mathematical patterns, including the percentage of their prescriptions that were paid for in cash.<sup>70</sup> This last parameter requires data in addition to Xponent®, which was not produced by labeler defendants. Physicians identified in this process were known as Region Zero physicians. For purposes of this evaluation, I reviewed only Xponent® sales data, though manufacturers have purchased or had access to additional data that would have given them even greater insight into prescribing and could have aided in their identification of potential diversion. For example, internal Purdue

---

<sup>65</sup> END00697783

<sup>66</sup> JAN-MS-01117436

<sup>67</sup> JAN-MS-01117436

<sup>68</sup> JAN-MS-01117436

<sup>69</sup> JAN-MS-02963355, JAN-MS-02963411, PPLP004418578 - PPLP004422062, PPLP004422064 - PPLP004422150

<sup>70</sup> PDD1503450011



communications showed that employees were analyzing pharmacies that were filling prescriptions by their Region Zero physicians.<sup>71</sup> Purdue referred to Region Zero physicians as “Physicians of Concern,” or those that they should not call upon due to suspicious prescribing patterns.<sup>72</sup>

80. Below is a table summarizing which labeler defendants purchased Xponent® data and whether they used it for marketing or sales tracking, to the best of my knowledge. Also included is a column indicating whether they used the data for compliance purposes. In my review of defendants’ produced documents, which I performed to the best of my ability, only Purdue and Qualitest mentioned using IQVIA data in any way for compliance and Janssen discusses using IQVIA data for one-off investigations of suspicious activity.

**Table 6 Purchase and Use of IQVIA Data by Labeler for Marketing and Compliance**

Parent Company	Labeler Name	Purchased IQVIA	Used IQVIA for Marketing	Used IQVIA for Compliance
INSYS	INSYS	Yes	Yes <sup>73</sup>	No
Endo	Endo	Yes	Yes	No <sup>74</sup>
	Par			No <sup>75</sup>
	Qualitest			No <sup>76</sup>
Mallinckrodt	Mallinckrodt	Yes	Yes	Yes <sup>77</sup>
Purdue	Purdue	Yes	Yes	Yes <sup>78</sup>
Teva	Actavis <sup>79</sup>	Yes	Yes	Yes <sup>80</sup>
	Allergan	Yes	Yes <sup>81</sup>	No
	Teva	Yes	Yes	Yes <sup>82</sup>
Johnson & Johnson	Janssen	Yes	Yes	No <sup>83</sup>

<sup>71</sup> PPLPC034000442027, PPLP004381385, PPLP004381385, PPLP004376811

<sup>72</sup> PPLPC020000823987

<sup>73</sup> 20180504 INSYS Response to Distr Rogs (008)

<sup>74</sup> Endo did not use IMS data for their SOMS program. Lisa Walker (who had responsibility for SOMS at Endo from 1997-2018 [Walker T. 53:5-54:10]) repeatedly testified that she did not use it, and that it was not her responsibility (L. Walker Tr. 190:1-5). Although the Opana ER RiskMAP and Generic Oxycodone ER RMP stated that Endo would review IMS data through the Risk Management Team or the Endo Safety Review Board, these teams were not compliance functions of the company, but rather Pharmacovigilance functions monitoring risks for drug safety and labeling purposes.

<sup>75</sup> Par’s SOMS program was deficient as of 2015. PAR\_OPIOID\_MDL\_0001024034, PAR\_OPIOID\_MDL\_0001596366. After it was acquired by Endo, it absorbed the Qualitest business, and adopted the Qualitest system PAR\_OPIOID\_MDL\_0001596366.

<sup>76</sup> Qualitest did use IMS data in its SOMS program, but in only connection with establishing thresholds for their wholesale customers, and only after 2013 (T. Norton Tr. 647:18-648:4, E. Brantley Tr. 679:11-20)

<sup>77</sup> MNK-T1\_0007204156, MNK-T1\_0007237561, MNK-T1\_0005503095

<sup>78</sup> PPLPC012000470917, PPLP003360551, PPLP003363479, PDD1503450011

<sup>79</sup> Teva acquired the Actavis/Watson generic pharmaceutical business from Allergan in 2016, and those entities are currently operating under the Teva SOMs system. Prior to 2016, the Actavis/Watson operated under Allergan’s SOMs system.

<sup>80</sup> Actavis used ValueCentric data when it was part of Allergan (see MDL\_01979834) and Teva used Valuecentric data as set forth below.

<sup>81</sup> ALLERGAN\_MDL\_02485011

<sup>82</sup> In 1998-2001 RMPs for ActiqCTIQ, Cephalon committed to the FDA that routinely monitor prescription data for inappropriate prescribing (TEVA\_CHI\_00049239, TEVA\_CHI\_00049269, TEVA\_CHI\_00049296).

<sup>83</sup> Janssen used chargeback and Valuetrack data on occasion for size only.

## 2. Results of Compliance Metric Application

81. The following tables summarize the overall results of applying the various compliance metrics used in distributors' and manufacturers' SOMS to the IQVIA data. Because physician totals count the distinct number of flagged physicians, they do not represent the full extent of potential "violations" of the metrics. In other words, the totals count a physician that was flagged by one compliance metric the same as a physician that tripped multiple compliance metrics multiple months in a row. This was not the case for dosage units or MMEs, which reflect the total amount of dosage units and MMEs flagged. However, the percent of physicians that were flagged indicates more concretely the severity of the metric application. The tables also indicate what percentage flagged transactions, dosage units, and MMEs comprised of Summit and Cuyahoga counties' total transactions, dosage units, and MMEs. Also included is a graph that visualizes how many dosage units were identified per compliance metric per year. Note that with this graph, as with every graph included in this report, because 2007 data was not included in the original production, the visualized 2007 values do not represent actual values, but are extrapolated by the visualization software. The data displayed in tables and used to develop this analysis did not estimate values for 2007. I also produce the results of applying the compliance metrics in Exhibit 2 – Results of Manufacturer to Prescriber Analysis Compliance Metric Application for each labeler, compliance metric, and year.

**Table 7 Flagging Results by Type of Compliance Metric (IQVIA; 1997-2006, 2008-2017 Summit, Cuyahoga)**

*Flagging totals are of defendant labelers and percentages are based on labeler's own share of prescriptions. The table is sorted by percent of county physicians.*

Metric	Defendant Labeler Flagged Physicians	% of Counties' Physicians	Defendant Labeler Flagged Prescriptions	% of Counties' Prescriptions	Defendant Labeler Flagged Dosage Units	% of Counties' Dosage Units	Defendant Labeler Flagged MMEs	% of Counties' MMEs
Common Sense	13,375	75.2	6,478,063	26.4	346,664,806	25.9	4,173,047,316	27.4
Double National Avg	7,441	41.9	13,240,306	54	752,860,314	56.3	9,323,502,171	61.3
Triple National Avg	5,526	31.1	10,677,069	43.6	628,269,023	47	8,095,048,941	53.2
McKesson 8,000	204	1.1	3,351,404	13.7	239,067,650	17.9	3,237,037,338	21.3
Any Metric	13,554	76.3	15,156,427	61.9	838,642,590	62.7	10,136,465,579	66.6

**Table 8 Number of Physicians Flagged by Compliance Metrics, by Labeler (IQVIA – Defendant Labelers; 1997-2006, 2008-2017 Summit, Cuyahoga)**

Labeler	Double National Avg	Triple National Avg	McKesson 8,000	Common Sense	Any Flag
Endo	5,864	4,329	195	10,926	11,073
INSYS	14	11	-	15	15
Johnson & Johnson	704	353	-	1,798	1,885
Mallinckrodt	6,038	4,448	200	12,044	12,173
Purdue	3,052	2,198	128	5,556	5,739
Teva	6,552	4,860	190	11,681	11,839

**Table 9 Total Prescriptions Flagged by Compliance Metrics, by Labeler**  
**(IQVIA – Defendant Labelers; 1997-2006, 2008-2017 Summit, Cuyahoga)**

Labeler	Double National Avg	Triple National Avg	McKesson 8,000	Common Sense	Any Flag
Endo	2,564,350	2,069,977	669,286	1,249,908	2,942,468
INSYS	696	675		175	702
Johnson & Johnson	94,549	75,773		70,250	122,011
Mallinckrodt	5,159,075	4,144,813	1,377,462	2,486,275	5,871,451
Purdue	680,343	594,419	265,832	342,320	749,057
Teva	4,741,293	3,791,412	1,038,824	2,329,135	5,470,738

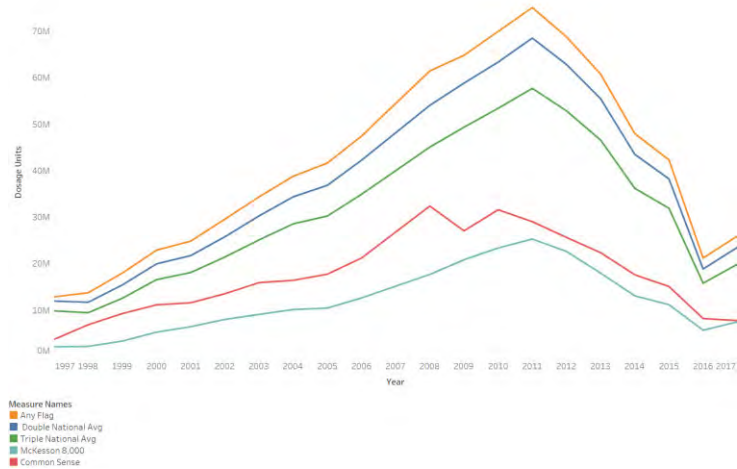
**Table 10 Number of Physicians Flagged by Compliance Metrics, by Specialty**  
**(IQVIA – Defendant Labelers; 1997-2006, 2008-2017 Summit, Cuyahoga)**

*Specialties sorted by the number of physicians that triggered any flag.*

Physician Specialty	Double National Avg	Triple National Avg	McKesson 8,000	Common Sense	Any Flag
Family/General	2,226	1,652	79	4,163	4,207
Dentistry	908	693	-	1,472	1,487
Surgery	913	752	31	1,478	1,482
Emergency/Critical	570	472	1	791	795
Obstetrics/Gynecology	378	255	2	584	586
Pediatrics	251	143	-	527	534
Psychiatry	124	70	3	421	424
Cardiology	203	131	1	393	403
Neurology	160	106	4	385	385
Anesthesiology	86	62	24	327	329
Other Specialty	166	120	-	326	328
Oncology	232	196	5	294	296
Ophthalmology	143	103	1	244	245
Radiology	81	49	-	217	224
Urology	122	100	-	201	201
Gastroenterology/Proctology	111	79	1	194	194
Pathology/Epidemiology	66	39	1	154	158
Dermatology	89	58	-	148	151
Unknown	26	22	10	136	136
Nephrology	78	49	-	131	131
Physical/Occupational Rehabilitation	69	51	7	125	125
Veterinary	49	30	1	92	109
Rheumatology	66	46	2	104	104
Pain Medicine	59	52	29	92	92
Pulmonology	42	32	-	87	87
Orthopedics	51	42	-	65	65
Geriatrics	40	25	1	59	61
Endocrinology	50	36	-	-	50
Administrative/Management	29	20	-	49	49
Allergy/Immunology	20	16	-	46	46
Hematology/Phlebotomy	16	14	1	21	21
Addiction	5	5	-	12	12
Sleep Medicine	2	1	-	11	11
Genetics	3	3	-	8	8
Aerospace/Hyperbaric/Nuclear	3	1	-	7	7
Hepatology	2	1	-	6	6
Medical Toxicology	1	-	-	2	2
Pharmacology	-	-	-	2	2
Nutrition	1	-	-	1	1
Research	-	-	-	-	-

**Figure 2 Number of Dosage Units Flagged by Compliance Metrics, Per Year  
(IQVIA – Defendant Labelers; 1997-2006, 2008-2017 Summit, Cuyahoga)**

*Note: for the Common Sense Flag, the dip in 2008 is caused by the missing 2007 data.*



82. Below is a table that, to the best of my knowledge, displays the physicians who were identified by labelers in Summit and Cuyahoga as suspicious or as physicians they were not to call on (e.g., Purdue Region Zero). To be included in the table, defendant labelers had to identify the prescriber before there were public reports of their misconduct. All the physicians triggered at least one, if not several, of the compliance metrics described above. To the best of my knowledge, despite a diligent search undertaken at my direction, there is no documentation indicating that labeler defendants reported any of these physicians to law enforcement or regulatory authorities.



**Table 11 Physicians Flagged by Labeler Defendants and Compliance Metrics**

First Name	Last Name	City	County	Labelers Identifying the Physician as Suspicious	Flagged by Compliance Metrics
Syed	Akhtar-Zaidi	Solon	Cuyahoga	Purdue <sup>84</sup>	Yes
Mark	Allen	Beachwood	Cuyahoga	Endo, <sup>85</sup> Purdue <sup>86</sup>	Yes
Ronald	Celeste	Mayfield Heights	Cuyahoga	Mallinckrodt 87	Yes
Adolph	Harper	Akron	Summit	Mallinckrodt, <sup>88</sup> Purdue <sup>89</sup>	Yes
William	Kerek	Akron	Summit	Purdue <sup>90</sup>	Yes
James	Lundeen	Mansfield	Cuyahoga	Mallinckrodt, <sup>91</sup> Endo, <sup>92</sup> Purdue <sup>93</sup>	Yes
Jorge	Martinez	Cleveland	Cuyahoga	Purdue <sup>94</sup>	Yes
Charles	Njoku	Akron	Summit	Endo <sup>95</sup>	Yes
David	Sassano	Cuyahoga Falls	Summit	Purdue <sup>96</sup>	Yes
Clive	Sinoff	Cleveland	Cuyahoga	Purdue <sup>97</sup>	Yes
Jean	Zannoni	Cleveland	Cuyahoga	Purdue <sup>98</sup>	Yes

83. These abbreviated case studies on individual prescribers is not meant to list of every suspicious prescriber in Cuyahoga and Summit counties, but to provide examples of the data that labelers had revealing suspicious physicians whose prescribing sent millions of pills into Cuyahoga and Summit counties. In many cases, based on internal documents, labelers actually knew of and continued to market to these prescribers.

### 3. Flagged Prescriber 1: Dr. Clive Sinoff

84. Located at 1001 Lakeside Avenue E in Cuyahoga County, Dr. Clive Sinoff tripped every compliance metric applied to IQVIA. The following section describes how Sinoff was flagged by the methodology and provides a profile of his prescribing patterns, as well as any known relevant contact he had with defendant manufacturers.

85. As a pain management specialist, Clive Sinoff prescribed mostly oxycodone, hydrocodone, and methadone to his patients. Prescribing patterns for all eight of the opioids Sinoff prescribed were uneven and volatile. All opioid prescriptions written by Sinoff precipitously dropped off after 2008, although there is no known explanation for this change. To date, no action has been taken against him and his license remains active.<sup>99</sup> However, Sinoff requested to withdraw his application to the Ohio Board of Pharmacy to register his practice as a pain clinic.<sup>100</sup> Sinoff made

<sup>84</sup> PPLP004474184, PPLPC012000283175

<sup>85</sup> ENDO-OPIOID\_MDL-01852639

<sup>86</sup> PPLPC012000283175

<sup>87</sup> 20190304 Cuyahoga Cty's Supp Response to Distr Rogs (002)

<sup>88</sup> 20190304 Cuyahoga Cty's Supp Response to Distr Rogs (002), MNK-T1\_0005947297

<sup>89</sup> PPLP004474184, PPLPC012000283175,

<sup>90</sup> PPLPC012000283175

<sup>91</sup> MNK-T1\_0005947297

<sup>92</sup> END00747479

<sup>93</sup> PPLP004474184, PPLPC012000283175

<sup>94</sup> PPLP004474184

<sup>95</sup> ENDO-OPIOID\_MDL-01852639

<sup>96</sup> PPLPC012000283175, PPLP004474184

<sup>97</sup> PPLPC012000283175, PPLP004474184

<sup>98</sup> PPLPC012000283175

<sup>99</sup> "Provider Information for 1801929849." NPPES NPI Registry, [npiregistry.cms.hhs.gov/registry/provider-view/1801929849](https://npiregistry.cms.hhs.gov/registry/provider-view/1801929849).

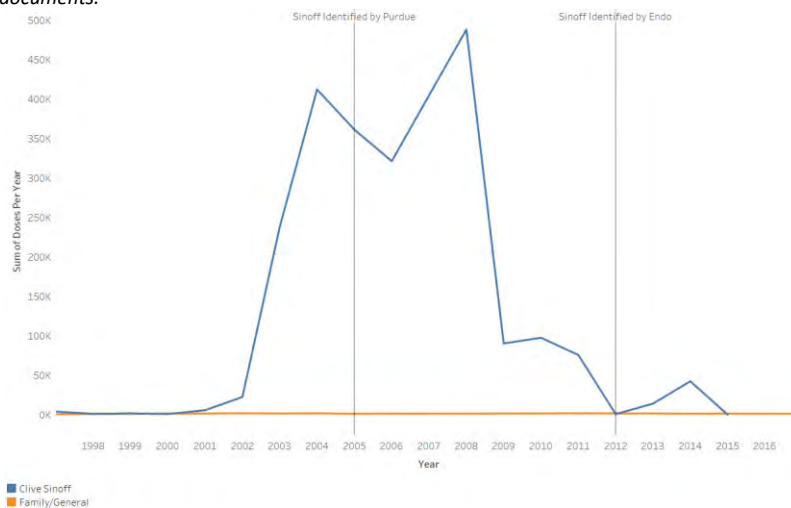
<sup>100</sup> OHIOPHARM00000061, OHIOPHARM00000058

this request in 2011 – the same year that he dramatically reduced his prescribing before stopping altogether.

86. Clive Sinoff wrote an extraordinary number of prescriptions even compared to a specialty group that would be expected to prescribe a higher volume of opioids. An anonymous patient spoke to the over-prescribing of Dr. Sinoff in an online review on September 4<sup>th</sup>, 2016: *"If I had taken all the meds he prescribed I would not be alive today."*<sup>101</sup> When the average pain management specialist in Ohio was writing less than 500 opioid prescriptions in 2003, Sinoff was writing 2,500 prescriptions. By 2008, when the average pain specialist was still writing less than 500 opioid prescriptions, Sinoff was writing roughly 7,000 prescriptions – approximately 27 prescriptions per business day, assuming he never took vacation. Included below is a chart visualizing the number of dosage units Sinoff wrote over time, shown in blue, compared to the statewide average among his specialty, shown in orange. The vertical lines represent dates at which Sinoff was identified as a suspicious prescriber by any defendant labeler, according to produced documents. As shown in the chart, Sinoff continued to prescribe for roughly five years after he was first identified as suspicious by Purdue.

**Figure 3 Physician Dosage Units Compared to Per Physician Specialty Average: Sinoff (IQVIA – all labelers; 1997-2006, 2008-2017)**

*The lines below identifying the year in which the physician was identified as suspicious are the earliest reference I could find in produced documents.*



87. Two of the three drugs that accounted for more than 5% of Sinoff's prescriptions were higher dose drugs. In fact, the opioid drug and dosage combination that Sinoff wrote the most prescriptions for was Purdue OxyContin 80mg. In comparison, pain management specialists typically write prescriptions for lower dose drugs, oxycodone 5mg and hydrocodone 5mg. Below is a table that displays the labeler and dosage for each drug that accounted for more than 5% of Sinoff's prescriptions.

<sup>101</sup> Sinoff, Clive L. "Pain Medicine." *Find a Doctor - Doctor Reviews and Ratings*, 4 Sept. 2016, [www.vitals.com/doctors/Dr\\_Clive\\_Sinoff.html](http://www.vitals.com/doctors/Dr_Clive_Sinoff.html).

**Table 12 Prescribing Overview by Labeler and Drug Dose: Sinoff  
(IQVIA – all labelers; 1997-2006, 2008-2017)**

*Because of rounding, totals for the same prescriber may reflect slightly different values because of differences in the levels of underlying aggregation (i.e., drug-level vs. labeler-level). This table was filtered for opioids greater than 5% of prescriptions and sorted by percent of prescriptions.*

Labeler	Drug and Dosage	Prescriptions	Prescriptions %	Dosage Units	Dosage Units %	MMEs	MMEs %
Purdue	Oxycodone 80mg	3,765	16.1	285,248	13.1	34,229,791	37.7
Purdue	Oxycodone 40mg	2,984	12.7	201,161	9.2	12,069,661	13.3
Endo	Oxycodone 10mg	1,484	6.3	186,845	8.6	2,802,677	3.1
Other Labelers	Other	15,174	64.0	1,509,904	68.6	41,674,731	45.5
<b>Total</b>		<b>23,407</b>		<b>2,183,158</b>		<b>90,776,860</b>	

88. Mallinckrodt and Purdue labeled more than half of all dosage units and MMEs that Sinoff prescribed. Internal documents from Purdue logged calls or visits to Sinoff at least 44 different times over the course of two years – between January 2004 through December 2005 – by sales representatives promoting OxyContin.<sup>102</sup> In 2006, Sinoff was ranked 84<sup>th</sup> on a list of top 500 OxyContin prescribers, according to Purdue documentation.<sup>103</sup> Between 2006 and 2008, his prescriptions of oxycodone almost doubled. As far as other defendant labelers were concerned, Sinoff was found in an internal Endo recruiter list for the marketing of long-acting opioids. Internal call logs showed that Sinoff was called on 25 different times in less than a year – from January through November 2008 – regarding Opana.<sup>104</sup> According to IQVIA, Sinoff began prescribing Opana ER in 2008 and continued to do so until 2011 when he closed his clinic. By 2012, Endo had deemed Sinoff a “do not call” doctor, placing him on the Endo Historical Removal list.<sup>105</sup> Sinoff was also considered to be a “Region Zero” prescriber by Purdue.<sup>106</sup> To the best of my knowledge, defendant labelers did not report Sinoff to authorities. Below is a table and chart that describe which defendants labeled the most opioids Sinoff prescribed in total and over time.

<sup>102</sup> PPLPMDL0080000001

<sup>103</sup> PPLPC012000283175

<sup>104</sup> ENDO\_OPIOID\_MDL\_00673566

<sup>105</sup> ENDO\_OPIOID\_MDL\_00673566

<sup>106</sup> PPLPC012000283175

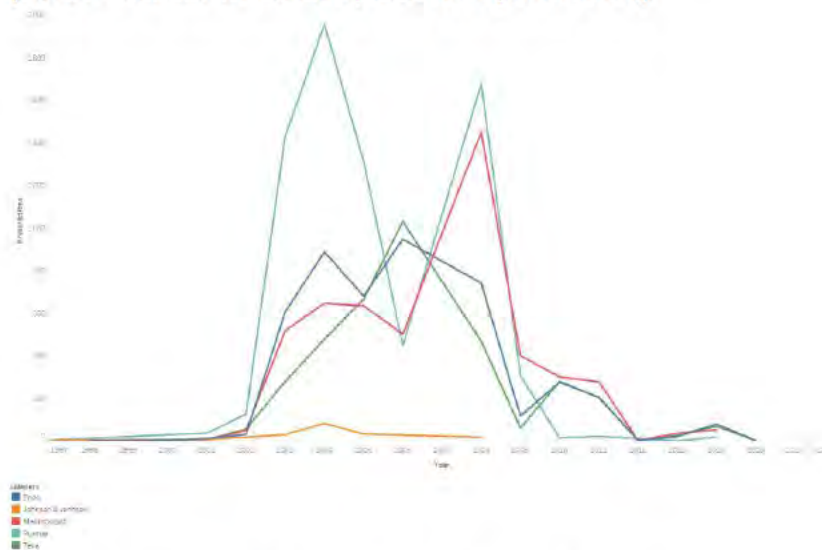


**Table 13 Prescribing by Labeler: Sinoff**  
**(IQVIA – all Labelers; 1997-2006, 2008-2017)**

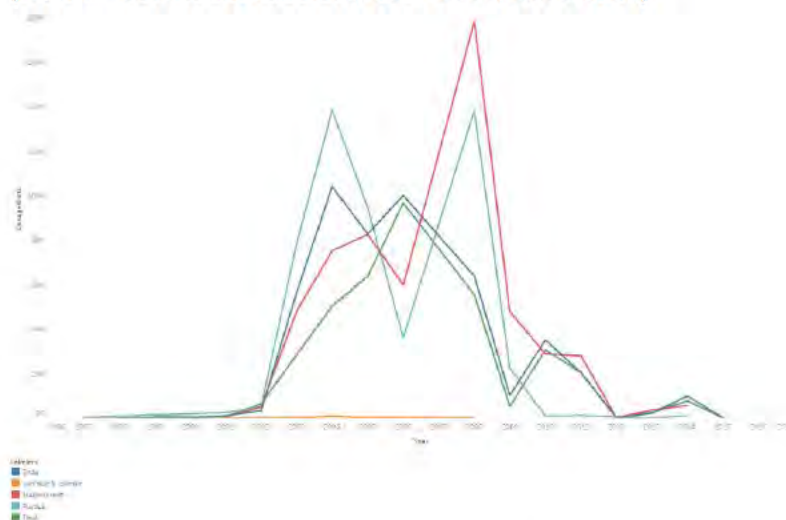
*Because of rounding, totals for the same prescriber may reflect slightly different values because of differences in the levels of underlying aggregation (i.e., drug-level vs. labeler-level). The table is sorted by percent of prescriptions.*

Labelers	Prescriptions	Prescription %	Dosage Units	Dosage Unit %	MMEs	MMEs %
Purdue	7,354	31.4	520,093	23.8	47,680,457	52.5
Mallinckrodt	4,871	23.5	564,209	28.9	11,668,054	13.6
Endo	4,610	22.2	490,712	25.1	13,591,045	15.9
Teva	3,625	17.5	370,133	18.9	12,186,426	14.2
Johnson & Johnson	169	0.8	1,689	0.1	11,529	0
Other Labelers	2,785	11.9	236,320	10.8	5,639,347	6.2
<b>Total</b>	<b>23,414</b>		<b>2,183,156</b>		<b>90,776,858</b>	

**Figure 4 Prescriptions by Labeler Over Time: Sinoff**  
**(IQVIA – Defendant Labelers; 1997-2006, 2008-2017)**



**Figure 5 Dosage Units by Labeler Over Time: Sinoff**  
**(IQVIA – Defendant Labelers; 1997-2006, 2008-2017)**



89. Sinoff triggered all four of the prescriber-applicable compliance metrics. He tripped the Common Sense compliance metric for all five of the labeler defendants' products, and the remaining metrics for four labeler defendants. Sinoff was flagged by Common Sense, Double and Triple National for more than half of his prescribing months of Mallinckrodt-, Teva- and Endo-labeled opioids. Below is a table that displays the percentage of total months during which Sinoff was prescribing that was flagged by the application of compliance metrics.

**Table 14 Percentage of Prescribing Months Flagged by Compliance Metric: Sinoff (IQVIA – defendant labelers; 1997-2006, 2008-2017)**

*Percentages are based on the number of total months the physician prescribed opioids from defendant labeler.*

Labeler	Common Sense	McKesson 8,000	Double National	Triple National	Any Flag
Endo	50.8	11.1	67.5	63.5	81.7
Johnson & Johnson	48.7	0	0	0	48.7
Mallinckrodt	57.1	11.8	68.1	65.5	86.6
Purdue	46.2	11.5	70.2	63.5	83.7
Teva	56.3	11.1	67.5	62.7	80.2

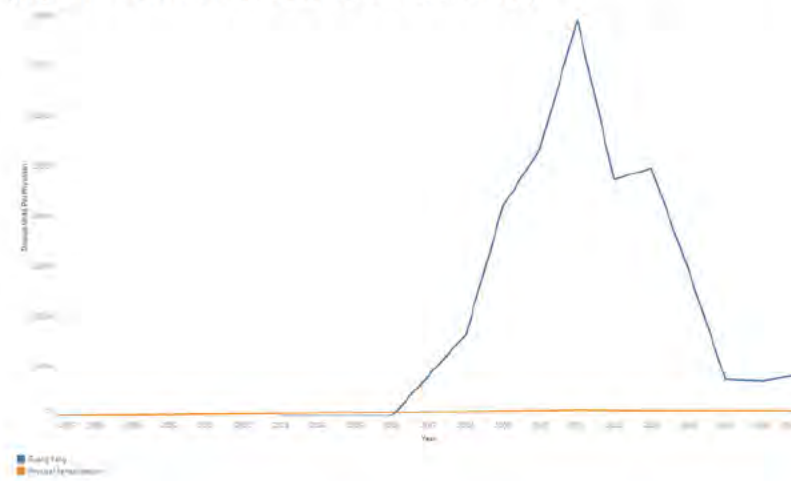
#### 4. Flagged Prescriber 2: Dr. Guang Yang

90. Located at 2215 E Waterloo Road in Akron, Dr. Guang Yang was another prescriber in the IQVIA data who tripped all prescriber-applied compliance metrics. The following section describes how Yang was flagged and provides a profile of his prescribing patterns, as well as any known relevant contact he had with labeler defendants.

91. Guang Yang wrote more than 42,000 opioid prescriptions in 2011 – an immense increase from less than 50 opioid prescriptions in 2006. If Yang had worked 24 hours a day for all 365 days of 2011, he would have written an average of 115 prescriptions per day, spending 12 minutes per patient – all while not sleeping. Yang's prescribing was not only in excess of his cohort but also of all prescribers in the country. In 2011, of the one million non-hospital prescribers nationwide, Yang was the second largest prescriber of opioids in the nation, according to IQVIA data. He was second only to Dr. Shelinder Aggarwal, who has since been sentenced to 15 years in prison for his prescribing behavior.<sup>107</sup> Of the 1.8 million prescribers in the IQVIA database for the full twenty-year period, Yang ranked 102<sup>nd</sup> for most opioid prescriptions written in total by a single physician. Included below is a chart visualizing the number of dosage units Yang wrote over time, shown in blue, compared to the statewide average among his specialty, shown in orange.

<sup>107</sup> "Huntsville Pill Mill Doctor Sentenced to 15 Years in Prison for Illegal Prescribing and Health Care Fraud." *The United States Department of Justice*, 7 Feb. 2017, [www.justice.gov/usao-ndal/pr/huntsville-pill-mill-doctor-sentenced-15-years-prison-illegal-prescribing-and-health](http://www.justice.gov/usao-ndal/pr/huntsville-pill-mill-doctor-sentenced-15-years-prison-illegal-prescribing-and-health).

**Figure 6 Physician Dosage Units Compared to Per Physician Specialty Average: Yang (IQVIA – all labelers; 1997-2006, 2008-2017)**



92. As a physical and occupational rehabilitation specialist, Guang Yang prescribed many different opioids – but the only combination of labeler product, drug, and dosage that made up more than 5% of his prescriptions was Mallinckrodt-labeled oxycodone 5mg, which alone made up more than 4% of all prescriptions of that product prescribed by rehab specialists in the state. This formulation was generally consistent with what was observed across his specialty; however, rehab specialists prescribed in much lower volume. Below is a table that displays the labeler and dosage for each drug that accounted for more than 5% of Yang's prescriptions.

**Table 15 Prescribing Overview by Labeler and Drug Dose: Yang (IQVIA – all labelers; 1997-2006, 2008-2017)**

*Because of rounding, totals for the same prescriber may reflect slightly different values because of differences in the levels of underlying aggregation (i.e., drug-level vs. labeler-level). This table was filtered for opioids greater than 5% of prescription and sorted by percent of prescriptions.*

Labeler	Drug and Dosage	Prescriptions	Prescriptions %	Dosage Units	Dosage Units %	MMEs	MMEs %
Mallinckrodt	Oxycodone 5mg	14,505	8.1	1,762,953	10.3	13,222,149	4.0
Other Labelers	Other	164,799	89.8	15,341,659	87.9	320,553,629	95.1
All Labelers		179,304		17,104,612		333,775,778	

93. More than one-third of all opioids prescribed by Yang were labeled by Mallinckrodt. Teva and Endo combined labeled almost as many Yang prescriptions as Mallinckrodt did alone. Yang was a target of almost every large labeler's marketing campaigns. Teva logged calls to Yang 115 times from 2006 to 2014.<sup>108</sup> Internal call records from Endo show that Yang was called 180 times by sales representatives from late 2008 through late 2016 for purposes of marketing Opana.<sup>109</sup> Additionally, internal Purdue documents show that Yang was called or visited by Purdue representatives at least 135 times from 2006 to 2017.<sup>110</sup> Mallinckrodt logged a minimum of 33 calls to Yang in 2011, 51 times in 2012, 44 times in 2013, and four times in 2014, mostly to market

<sup>108</sup> TEVA\_MDL\_A\_02416207

<sup>109</sup> ENDO OPIOID MDL 00673566

<sup>110</sup> PPLPMDL0020000001



Exalgo.<sup>111</sup> In fact, Yang was listed as a “Top Managed Care Opportunities” for internal training purposes at Mallinckrodt and was considered to be an “Exalgo 3 Star Prescriber.”<sup>112</sup> To the best of my knowledge, defendant labelers did not identify Yang as suspicious or report Yang to authorities. Below is a table and chart that describe which defendants labeled the most opioids Yang prescribed both in total and over time.

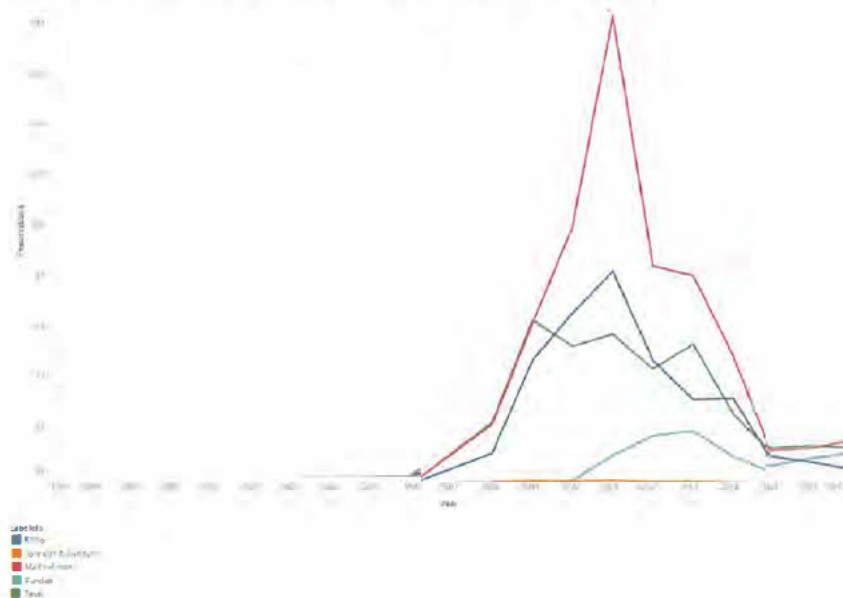
#### Prescribing by Labeler: Yang

(IQVIA – all Labelers; 1997-2006, 2008-2017)

*Because of rounding, totals for the same prescriber may reflect slightly different values because of differences in the levels of underlying aggregation (i.e., drug-level vs. labeler-level). The table is sorted by percent of prescriptions.*

Labelers	Prescriptions	Prescription %	Dosage Units	Dosage Unit %	MMEs	MMEs %
Mallinckrodt	63,049	35.2	6,593,217	38.5	108,753,990	32.6
Teva	36,673	20.5	3,853,029	22.5	57,941,878	17.4
Endo	34,480	19.2	3,298,427	19.3	96,717,823	29.0
Purdue	763	0.4	104,544	0.6	1,732,051	0.5
Johnson & Johnson	649	0.4	7,804	0	51,105	0
Other Labelers	43,697	24.4	3,247,597	19	68,578,928	20.5
<b>Total</b>	<b>179,311</b>		<b>17,104,618</b>		<b>333,775,775</b>	

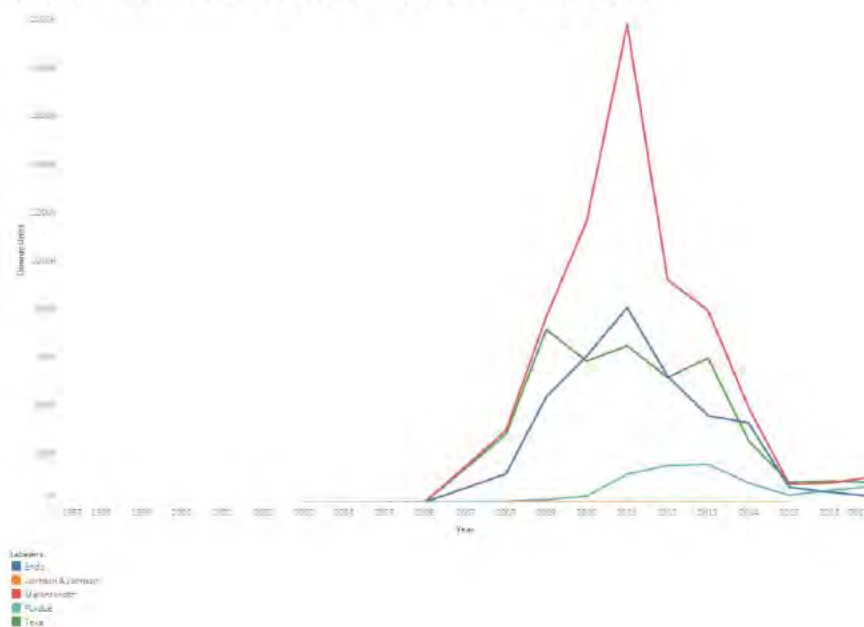
**Figure 7 Prescriptions by Labeler Over Time: Yang**  
(IQVIA – Defendant Labelers; 1997-2006, 2008-2017)



<sup>111</sup> MNK T1 0001029479, MNK T1 0001029480, MNK T1 0001029481, MNK-T1 0001029482

<sup>112</sup> MNK T1 0001029479

**Figure 8 Dosage Units by Labeler Over Time: Yang  
(IQVIA – Defendant Labelers; 1997-2006, 2008-2017)**



94. Yang triggered all four of the prescriber-applicable compliance metrics for every combination of labeler and metric except for prescriptions of Johnson & Johnson-labeled opioids as captured by the McKesson 8,000 compliance metric, as Johnson & Johnson did not produce (and thus provide chargebacks for) hydrocodone or oxycodone opioids. Yang was flagged for more than 90% of months he was prescribing Endo-, Mallinckrodt-, and Teva-labeled opioids, according to the Double and Triple National compliance metrics. That Yang was most frequently flagged for exceeding the threshold metrics (Double and Triple National Averages, McKesson 8,000) would be consistent with his status as an extremely high volume prescriber. Below is a table that displays the percentage of total months during which Yang was prescribing that were flagged by the application of the compliance metrics.

**Table 16 Percentage of Prescribing Months Flagged by Compliance Metric: Yang  
(IQVIA – defendant labelers; 1997-2006, 2008-2017)**

*Percentages are based on the number of total months the physician prescribed opioids from defendant labeler.*

Labeler	Common Sense	McKesson 8,000	Double National	Triple National	Any Flag
Endo	49.2	88.5	95.9	95.9	98.4
Johnson & Johnson	17.7	0	96.2	94.9	96.2
Mallinckrodt	48.8	85	92.1	92.1	96.1
Purdue	22.2	61.1	98.9	98.9	98.9
Teva	52.4	85.7	92.9	92.9	96.8

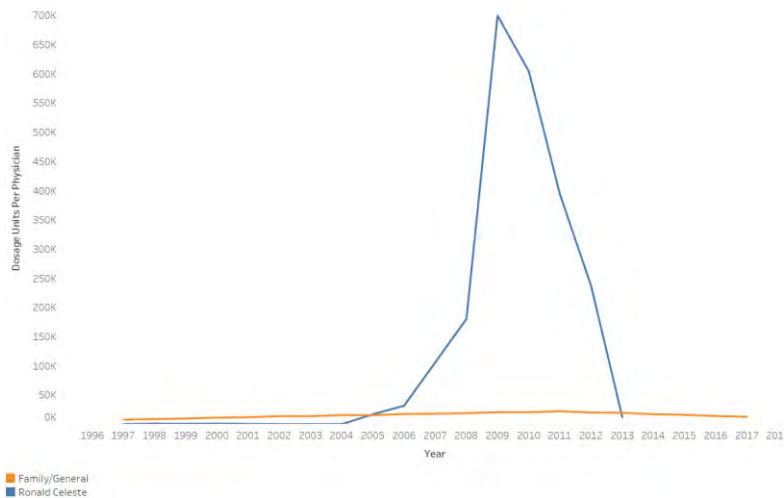
## 5. Flagged Prescriber 3: Dr. Ronald Celeste

95. Located at 6780 Mayfield Road in Mayfield Heights, Dr. Ronald Celeste was another prescriber in the IQVIA data who tripped all compliance metrics applied to IQVIA. The following section describes how Celeste was flagged and provides a profile of his prescribing patterns, as well as any known relevant contact he had with labeler defendants.

96. A family practitioner in Cuyahoga County, Ronald Celeste wrote prescriptions for drugs and dosages that were relatively consistent with others in his specialty. He wrote the greatest number of opioid prescriptions for two Mallinckrodt and Teva products of the same drug and dosage type – hydrocodone 7.5mg. However, Celeste’s prescribing activity over time was irregular. Celeste’s prescriptions skyrocketed in 2007, peaking at almost 8,000 opioid prescriptions in 2008 – when other family practitioners were writing less than 500 prescriptions on average. The bulk of his prescriptions for defendant-labeled opioids were written between 2008 and 2011, when they rapidly declined before ceasing altogether. Such a dramatic uptick in prescriptions caught the attention of authorities, who launched a two-year investigation into his practice in 2014.<sup>113</sup> Celeste was recently sentenced to three years in prison for illegally writing tens of thousands of prescriptions between 2009 and 2011 alone.<sup>114</sup> Included below is a chart visualizing the number of dosage units Celeste wrote over time, shown in blue, compared to the statewide average among his specialty, shown in orange. The table that follows breaks down his prescribing patterns by opioid drug and dosages that accounted for more than 5% of his total prescriptions.

**Figure 9 Physician Dosage Units Compared to Per Physician Specialty Average: Celeste (IQVIA – all labelers; 1997-2006, 2008-2017)**

*Celeste was identified by Mallinckrodt as suspicious, but I do not have dates for when that identification was made. The lines below identifying the year in which the physician was identified as suspicious are the earliest reference I could find in produced documents.*



<sup>113</sup> "Pill Mill Doctor Headed for Prison." *Pill Mill Doctor Headed for Prison - Cuyahoga County Prosecutor*, prosecutor.cuyahogacounty.us/en-US/SYN//70973/NewsDetailTemplate.aspx.

<sup>114</sup> Shaffer, Cory. "Westlake Doctor Sentenced to Prison for Running 'Pill Mill'." *Cleveland.com*, Cleveland.com, 5 Apr. 2016, www.cleveland.com/metro/2016/04/westlake\_doctor\_sentenced\_to\_p.html.

**Table 17 Prescribing Overview by Labeler and Drug Dose: Celeste**  
**(IQVIA – all labelers; 1997-2006, 2008-2017)**

*Because of rounding, totals for the same prescriber may reflect slightly different values because of differences in the levels of underlying aggregation (i.e., drug-level vs. labeler-level). This table was filtered for opioids greater than 5% of prescriptions and sorted by percent of prescriptions.*

Labeler	Drug and Dosage	Prescriptions	Prescriptions %	Dosage Units	Dosage Units %	MMEs	MMEs %
Mallinckrodt	Oxycodone 5mg	2,999	12.1	291,797	13.4	2,188,476	4.4
Teva	Oxycodone 10mg	1,851	7.5	190,461	8.7	2,856,912	5.8
Mallinckrodt	Hydrocodone 7.5mg	1,264	5.1	121,544	5.6	911,584	1.8
Teva	Hydrocodone 7.5mg	1,252	5.1	119,570	5.5	896,771	1.8
Other Labelers	Other	17,351	69.7	1,455,473	66.2	42,452,189	85.8
<b>All Labelers</b>		<b>24,717</b>		<b>2,178,845</b>		<b>49,305,932</b>	

97. Most opioids purchased by Celeste were labeled by Teva and Mallinckrodt, which together labeled roughly two-thirds of all opioids prescribed by Celeste. Endo logged over 100 different calls on Celeste over the course of the five years between 2008 and 2013.<sup>115</sup> Mallinckrodt internal documentation also showed that Celeste was marked as a high strength opioid prescriber, which meant he could be counted on to write at least 20 prescriptions a month of 120 MMEs per day. To the best of my knowledge, Endo never identified Celeste as a suspicious prescriber. However, Mallinckrodt identified him at some point in time as potentially problematic. To the best of my knowledge, defendant labelers did not report Celeste to authorities. Below is a table and chart that describe which defendants labeled the most opioids Celeste prescribed, both in total and over time.

**Figure 10 Prescribing by Labeler: Celeste**  
**(IQVIA – all Labelers; 1997-2006, 2008-2017)**

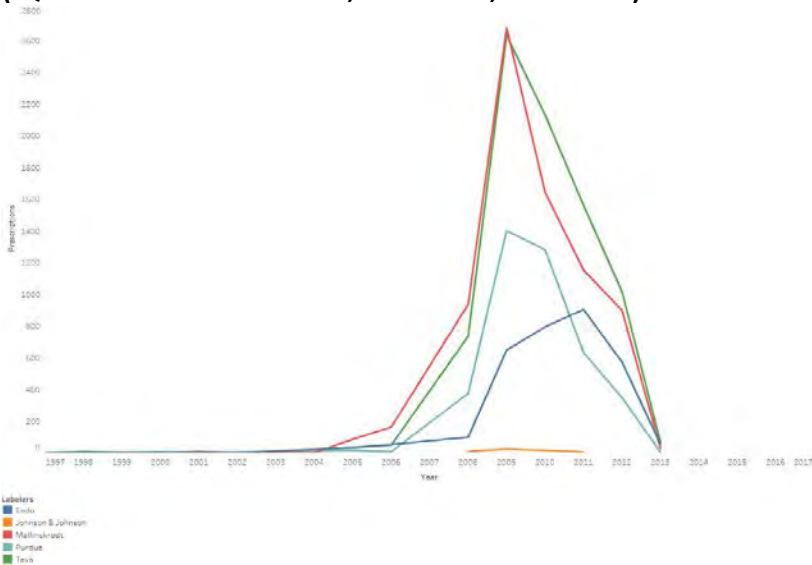
*Because of rounding, totals for the same prescriber may reflect slightly different values because of differences in the levels of underlying aggregation (i.e., drug-level vs. labeler-level). The table is sorted by percent of prescriptions.*

Labelers	Prescriptions	Prescription %	Dosage Units	Dosage Unit %	MMEs	MMEs %
Teva	8,251	33.4	754,985	34.7	10,327,291	20.9
Mallinckrodt	7,609	30.8	718,262	33.0	7,965,136	16.2
Purdue	4,011	16.2	289,518	13.3	22,243,659	45.1
Endo	3,180	12.9	290,315	13.3	6,342,531	12.9
Johnson & Johnson	60	0.2	588	-	3,645	-
Other	1,605	6.5	125,172	5.7	2,423,669	4.9
<b>Total</b>	<b>24,716</b>		<b>2,178,840</b>		<b>49,305,931</b>	

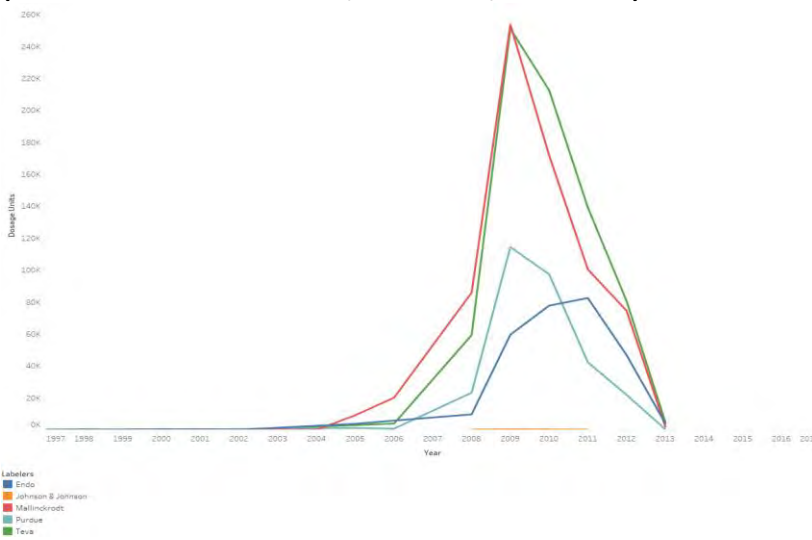
<sup>115</sup> ENDO\_OPIOID\_MDL\_00673566



**Figure 11 Prescriptions by Labeler Over Time: Celeste (IQVIA – Defendant Labelers; 1997-2006, 2008-2017)**



**Figure 12 Dosage Units by Labeler Over Time: Celeste (IQVIA – Defendant Labelers; 1997-2006, 2008-2017)**



98. Celeste triggered all IQVIA compliance metrics with varying frequencies, the only exception being the McKesson 8,000 compliance metric for his Johnson & Johnson prescriptions. He was flagged for the highest percentage of months across all labelers by the Double National Average compliance metric, triggering it for as high as 93% of the months he wrote opioid prescriptions. Below is a table that displays the percentage of total months during which Celeste was prescribing that was flagged by the application of the compliance metrics.

**Table 18 Percentage of Prescribing Months Flagged by Compliance Metric: Celeste (IQVIA – defendant labelers; 1997-2006, 2008-2017)**

*Percentages are based on the number of total months the physician prescribed opioids from defendant labeler.*

Labeler	Common Sense	McKesson 8,000	Double National	Triple National	Any Flag
Endo	59.0	31.0	79.0	74.0	91.0
Johnson & Johnson	30.0	-	46.7	13.3	60.0
Mallinckrodt	57.8	30.4	76.5	72.5	87.3
Purdue	41.3	41.3	93.3	89.3	97.3
Teva	54.8	29.8	64.4	60.6	78.8

6. Flagged Prescriber 4: Dr. James Lundeen

99. Located at 1 Marion Avenue in Mansfield, OH, Dr. James Lundeen was another prescriber in the IQVIA data who tripped most IQVIA compliance metrics. The following section describes how Lundeen was flagged and provides a profile of his prescribing patterns, as well as any relevant known contact he had with labeler defendants.

100. An anesthesiologist, Lundeen most often prescribed hydrocodone 10mg and 7.5mg. The prescription written most by the average Ohio anesthesiologist was for half the strength. Almost half of all his prescriptions were attributed to Teva, Mallinckrodt, and one non-defendant labeler (Abbvie). James Lundeen surrendered his license to the Ohio State Medical Board in 2011 on the ground that he had overprescribed opioids across the state; he reportedly operated out of 12 different offices in Ohio and saw up to 90 patients per day.<sup>116</sup> His address and even county locations changed several times throughout the IQVIA data. Lundeen was first identified as a suspicious prescriber in 2003 by Purdue.<sup>117</sup> Endo also removed Lundeen from call lists in 2011.<sup>118</sup> To the best of my knowledge, no labeler reported Lundeen to authorities. Below are tables that display the labeler and dosage for each drug that accounted for more than 5% of Lundeen's prescriptions. Also included is a chart visualizing the number of total dosage units Lundeen wrote over time, shown in blue, compared to the statewide average among his specialty, shown in orange. The vertical line represents the year Lundeen was identified as a suspicious prescriber by Purdue. As shown in the chart, Lundeen continued to prescribe for almost ten years after he was first identified as suspicious by Purdue.

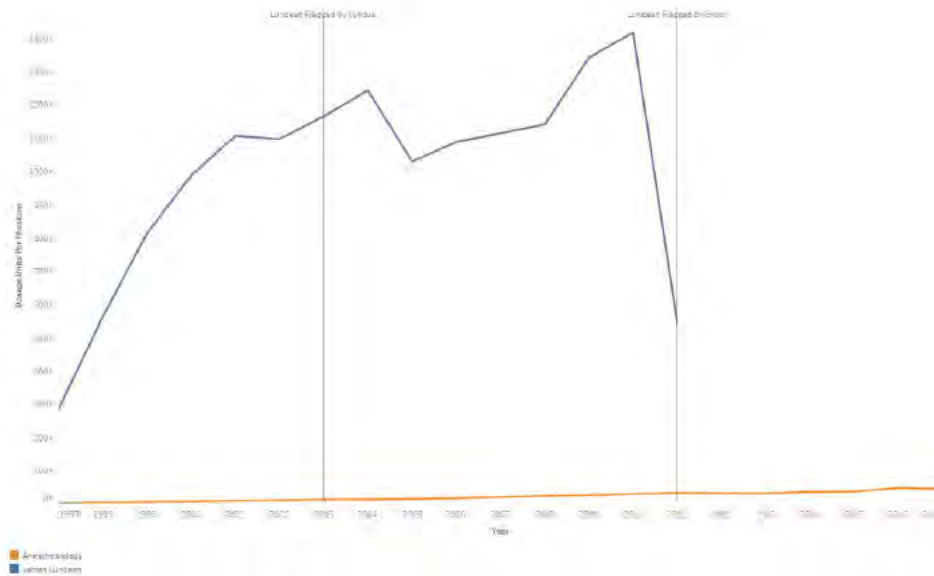
<sup>116</sup> Johnson, Alan, and Columbus Dispatch. "Pain Doctor Can't Work in Ohio Anymore." *The Columbus Dispatch*, The Columbus Dispatch, 15 Dec. 2011, [www.dispatch.com/article/20111215/NEWS/312159761](http://www.dispatch.com/article/20111215/NEWS/312159761).

<sup>117</sup> PPLP004474184\_HIGHLY CONFIDENTIAL, PPLPC012000283175

<sup>118</sup> END00747479

**Figure 13 Physician Dosage Units Compared to Per Physician Specialty Average: Lundeen (IQVIA – all labelers; 1997-2006, 2008-2017)**

Lundeen was also identified by Mallinckrodt as suspicious, but I do not have dates for when that identification was made. The lines below identifying the year in which the physician was identified as suspicious are the earliest reference I could find in produced documents.



**Table 19 Prescribing Overview by Labeler and Drug Dose: Lundeen (IQVIA – all labelers; 1997-2006, 2008-2017)**

Because of rounding, totals for the same prescriber may reflect slightly different values because of differences in the levels of underlying aggregation (i.e., drug-level vs. labeler-level). This table was filtered for opioids greater than 5% of prescriptions and sorted by percent of prescriptions.

Labeler	Drug and Dosage	Prescriptions	Prescriptions %	Dosage Units	Dosage Units %	MMEs	MMEs %
Teva	Hydrocodone 10mg	14,781	11.2	1,871,578	13.5	18,715,781	12.0
Mallinckrodt	Hydrocodone 10mg	14,258	10.8	1,728,809	12.5	17,288,087	11.1
Mallinckrodt	Hydrocodone 7.5mg	13,333	10.1	1,409,854	10.2	10,573,909	6.8
Teva	Hydrocodone 7.5mg	12,768	9.7	1,228,765	8.9	9,215,737	5.9
Abbvie	Hydrocodone 7.5mg	8,083	6.1	747,821	5.4	5,608,659	3.6
Endo	Oxycodone 10mg	6,724	5.1	840,012	6.1	12,600,186	8.1
Other	Other	62,003	46.2	5,997,433	42.1	81,402,601	51.6
<b>All Labelers</b>		<b>131,950</b>		<b>13,824,272</b>		<b>155,404,960</b>	

101. Although his prescriptions were heavily concentrated among Teva and Mallinckrodt, Lundeen wrote thousands of prescriptions for opioids labeled by other defendants. Endo and Teva both pursued Lundeen as a marketing target. Endo logged a minimum of 88 calls to Lundeen at which it promoted Opana ER.<sup>119</sup> Teva also pursued Lundeen as a marketing target, with internal

<sup>119</sup> ENDO-OPIOID\_MDL-00673566

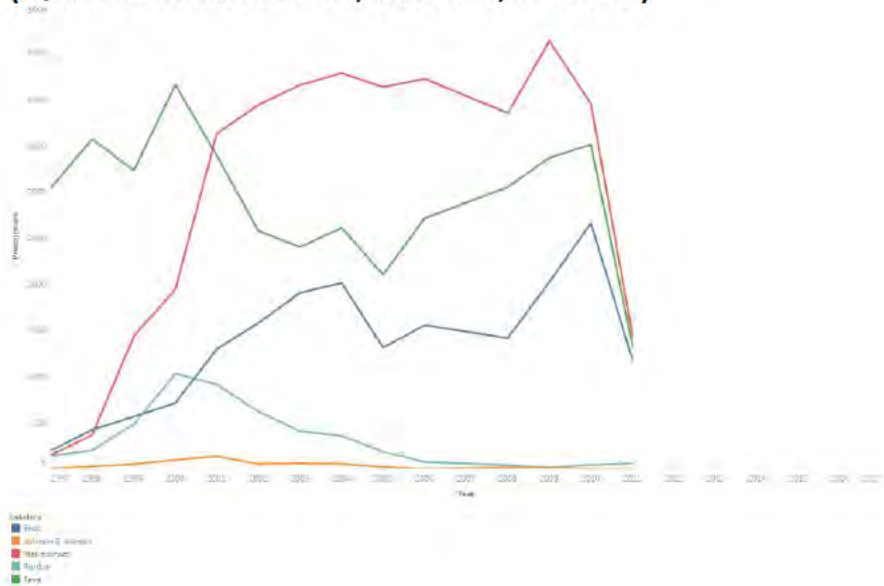
documentation showing 36 calls between 2002 and 2005.<sup>120</sup> According to internal documents from each of the labeler defendants Janssen, Mallinckrodt, and Purdue identified Lundeen as a suspicious prescriber.<sup>121</sup> To the best of my knowledge, defendant labelers did not report Lundeen to authorities. Below is a table and chart that describe which defendants labeled the most opioids Lundeen prescribed, in total and over time.

**Table 31 Prescribing by Labeler: Lundeen**  
(IQVIA – all Labelers; 1997-2006, 2008-2017)

*Because of rounding, totals for the same prescriber may reflect slightly different values because of differences in the levels of underlying aggregation (i.e., drug-level vs. labeler-level). The table is sorted by percent of prescriptions.*

Labelers	Prescriptions	Prescription %	Dosage Units	Dosage Unit %	MMEs	MMEs %
Teva	42,157	31.9	4,638,725	33.6	43,222,543	27.8
Mallinckrodt	41,060	31.1	4,432,484	32.1	41,510,371	26.7
Purdue	18,839	14.3	2,064,595	14.9	27,849,395	17.9
Endo	4,142	3.1	257,313	1.9	11,836,920	7.6
Johnson & Johnson	521	0.4	5,785	0	48,560	0
Other	25,235	19.1	2,425,375	17.5	30,937,170	19.9
<b>Total</b>	<b>131,954</b>		<b>13,824,277</b>		<b>155,404,959</b>	

**Figure 14 Prescriptions by Labeler Over Time: Lundeen**  
(IQVIA – Defendant Labelers; 1997-2006, 2008-2017)

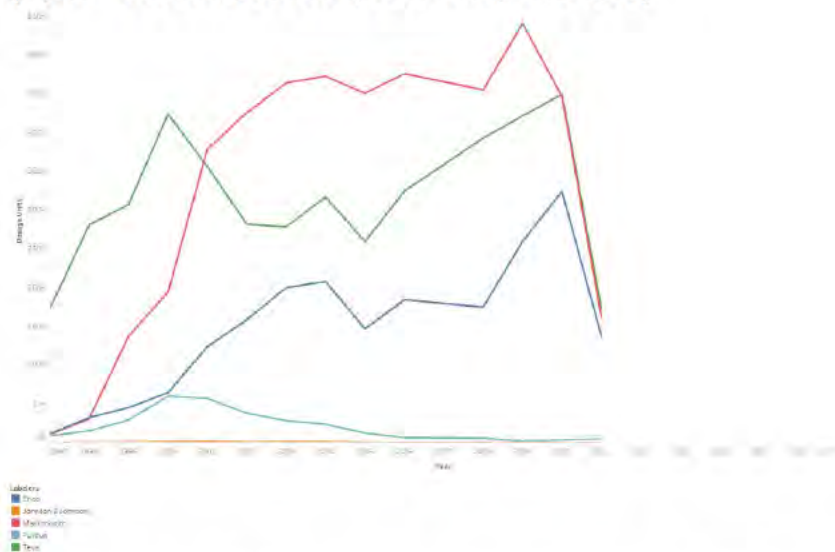


<sup>120</sup> TEVA\_MDL\_A\_02416207

<sup>121</sup> PPLP004474184\_HIGHLY CONFIDENTIAL, PPLPC012000283175, Janssen ROG response, 2019.03.13\_Ohio.HCPs.diversion.Compliance.Dept.FINAL, ENDO00747479, MNK-T1\_0005947297



**Figure 15 Dosage Units by Labeler Over Time: Lundeen  
(IQVIA – Defendant Labelers; 1997-2006, 2008-2017)**



102. Lundeen triggered all compliance metrics applied to prescribers. He was flagged for nearly 100% of his total prescriptions by many labeler and metric combinations: Double and Triple National Average for Endo-, Mallinckrodt-, and Teva-labeled opioids, as well as McKesson 8,000 for the same three labelers. Similar to other physician examples, the only labeler and compliance metric combination he did not trigger was McKesson 8,000 for Johnson & Johnson. Below is a table that displays the percentage of total months during which Lundeen was prescribing that was flagged by the application of the compliance metrics.

**Table 20 Percentage of Prescribing Months Flagged by Compliance Metric: Lundeen  
(IQVIA – defendant labelers; 1997-2006, 2008-2017)**

*Percentages are based on the number of total months the physician prescribed opioids from defendant labeler.*

Labeler	Common Sense	McKesson 8,000	Double National	Triple National	Any Flag
Endo	68.5	96.4	98.8	98.2	98.8
Johnson & Johnson	30.8	-	15.9	1.9	41.1
Mallinckrodt	65.7	95.8	98.2	97.6	98.2
Purdue	41.8	57.4	98.4	89.3	98.4
Teva	66.7	96.4	98.8	98.2	98.8

## 7. Flagged Prescriber 5: Dr. Adolph Harper

103. Located at 2569 Romig Road in Akron, Dr. Adolph Harper was another prescriber in the IQVIA data who tripped every compliance metric applied to IQVIA data. The following section describes how Harper was flagged and provides a profile of his prescribing patterns, as well as any known relevant contact he had with labeler defendants.

104. A gynecologist in Akron, Adolph Harper surrendered his license in May 2012 after state and federal authorities determined he was illegally prescribing opioids and operating a “pill mill.”<sup>122</sup>

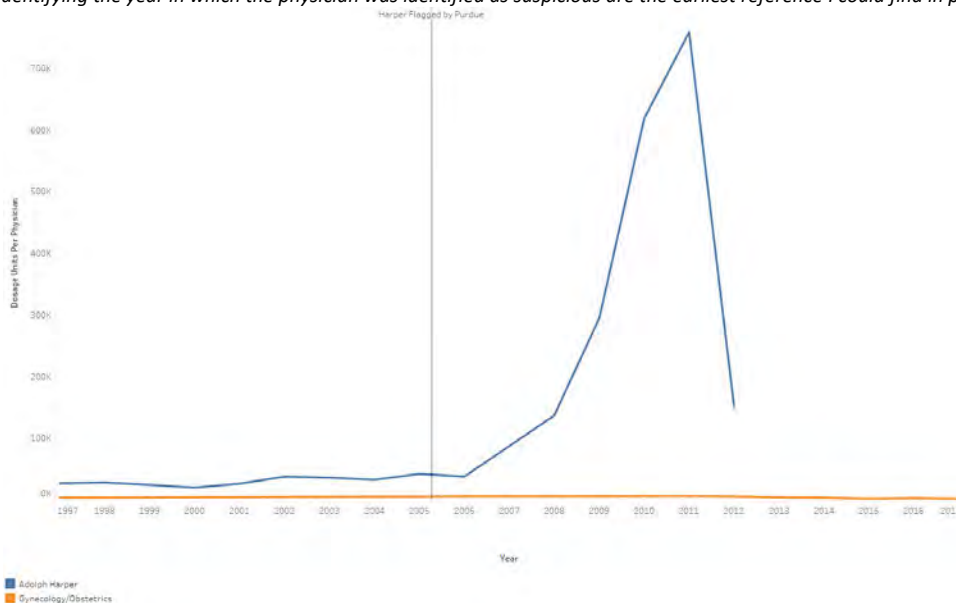
<sup>122</sup> 20190304 Summit Akron Suppl Resp Obj to Distr Def ROG (002)

Harper most often prescribed oxycodone: all of the opioids he wrote at greater than 5% of his total prescriptions were oxycodone products, two of which were of higher dosage strength. Oxycodone 80mg pills accounted for more than 6% of all of his prescriptions. Compared to other gynecologists in Ohio, this deviated substantially from the norm. On average, Ohio gynecologists typically wrote a mix of low dose prescriptions for oxycodone, hydrocodone, and codeine.

105. Harper pled guilty in 2014 to counts that included conspiracy to traffic drugs, health care fraud, and sixteen separate counts of drug trafficking. Purdue first recommended that representatives cease to call on Harper in 2005.<sup>123</sup> Below are tables that display the labeler and dosage for each drug that accounted for more than 5% of Harper's prescriptions. Also included is a chart visualizing the number of total prescriptions Harper wrote over time, shown in blue, compared to the statewide average among his specialty, shown in orange. The vertical lines represent dates at which Harper was identified as a suspicious prescriber by any defendant labeler, according to produced documents. As shown in the chart, Harper continued to prescribe in high volume subsequent to these dates.

**Figure 16 Physician Dosage Units Compared to Per Physician Specialty Average: Harper (IQVIA – all labelers; 1997-2006, 2008-2017)**

*Harper was also identified by Mallinckrodt as suspicious, but I do not have dates for when that identification was made. The lines below identifying the year in which the physician was identified as suspicious are the earliest reference I could find in produced documents.*



<sup>123</sup> PPLP004474184, PPLPC012000283175

**Table 21 Prescribing Overview by Labeler and Drug Dose: Harper**  
**(IQVIA – all labelers; 1997-2006, 2008-2017)**

*Because of rounding, totals for the same prescriber may reflect slightly different values because of differences in the levels of underlying aggregation (i.e., drug-level vs. labeler-level). This table was filtered for opioids greater than 5% of prescriptions and sorted by percent of prescriptions.*

Labeler	Drug and Dosage	Prescriptions	Prescriptions %	Dosage Units	Dosage Units %	MMEs	MMEs %
Mallinckrodt	Oxycodone 5mg	4,361	12.5	247,678	10.9	1,857,582	3.3
Teva	Oxycodone 10mg	3,976	11.4	407,633	17.9	6,114,489	11.0
Teva	Oxycodone 5mg	2,424	7.0	132,541	5.8	994,054	1.8
Purdue	Oxycodone 80mg	2,107	6.1	74,153	3.3	8,898,313	16.0
Purdue	Oxycodone 40mg	1,879	5.4	71,719	3.2	4,303,146	7.8
Other Labelers	Other	20,066	57	1,338,296	58.2	33,356,840	59.5
<b>All Labelers</b>		<b>34,813</b>		<b>2,272,020</b>		<b>55,524,424</b>	

106. Most prescriptions written by Harper were for Teva- and Mallinckrodt-labeled opioids, which together accounted for roughly 70% of all dosage units Harper prescribed. Between 1997 and 2001, sales representatives from Purdue logged 109 calls to Harper regarding OxyContin. Purdue continued to call on him until a sales representative reported him as suspicious in 2005 and suggested that he not be called upon.<sup>124</sup> Beginning in 2008 Endo began detailing Harper for Opana ER, with logs showing that representatives contacted him at least 117 times in less than four years.<sup>125</sup> Teva also targeted Harper for marketing, logging visits to him 24 times between 2004 and 2005.<sup>126</sup> To the best of my knowledge, defendant labelers did not report Harper to authorities. Below is a table and chart that describe which labeler defendants labeled the most opioids Harper prescribed, in total and over time.

**Table 22 Prescribing by Labeler: Harper**  
**(IQVIA – all Labelers; 1997-2006, 2008-2017)**

*Because of rounding, totals for the same prescriber may reflect slightly different values because of differences in the levels of underlying aggregation (i.e., drug-level vs. labeler-level). The table is sorted by percent of prescriptions.*

Labelers	Prescriptions	Prescription %	Dosage Units	Dosage Unit %	MMEs	MMEs %
Teva	10,744	30.9	796,405	35.1	11,182,907	20.1
Mallinckrodt	9,204	26.4	599,248	26.4	7,769,616	14.0
Endo	5,811	16.7	421,734	18.6	17,220,541	31.0
Purdue	5,129	14.7	180,054	7.9	14,827,229	26.7
Johnson & Johnson	1	0	15	0	37	0
Other	3,927	11.3	274,565	12.1	4,524,095	8.1
<b>Total</b>	<b>34,816</b>		<b>2,272,021</b>		<b>55,524,425</b>	

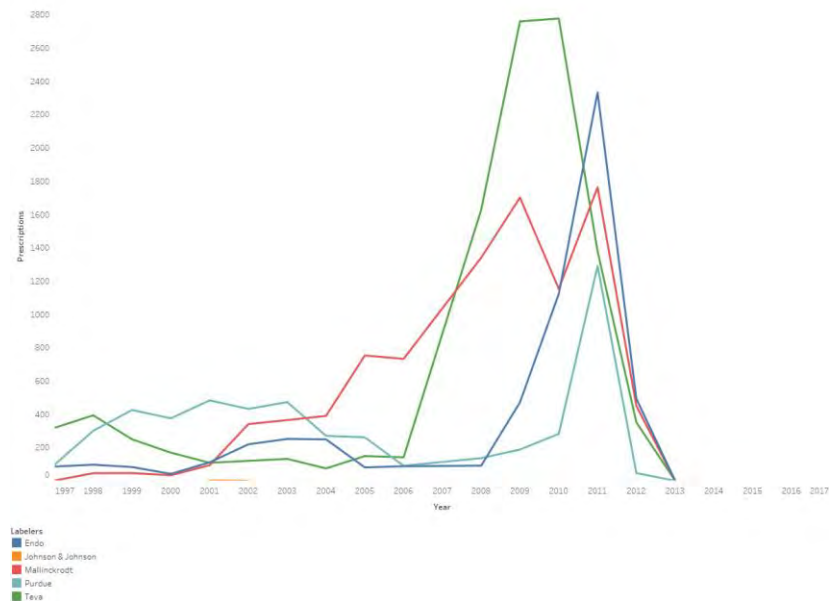
<sup>124</sup> PPLPMDL0030005334, PPLPMDL0030005327

<sup>125</sup> ENDO\_OPIOID\_MDL\_00673566

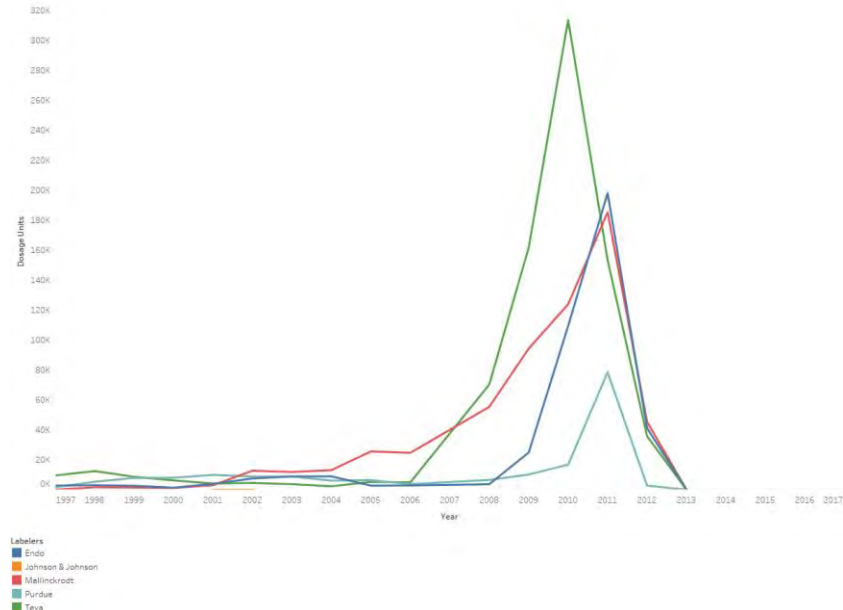
<sup>126</sup> TEVA\_MDL\_A\_02416207



**Figure 17 Prescriptions by Labeler Over Time: Harper  
(IQVIA – Defendant Labelers; 1997-2006, 2008-2017)**



**Figure 18 Dosage Units by Labeler Over Time: Harper  
(IQVIA – Defendant Labelers; 1997-2006, 2008-2017)**



107. Harper was captured by all four compliance metrics applied to prescribers for every defendant labeler except Johnson & Johnson. However, according to IQVIA data, Harper only prescribed Johnson & Johnson for one month of his career. Harper tripped the Double National and Triple National Average metrics for nearly 100% of months he prescribed the products of every labeler, except Johnson & Johnson. He was flagged for roughly one-fourth of all months he prescribed Endo-, Mallinckrodt-, Purdue-, and Teva-labeled opioids for the 8,000 dosage units threshold.

Below is a table that displays the percentage of total months during which Harper was prescribing that were flagged by the application of the compliance metrics.

**Table 23 Percentage of Prescribing Months Flagged by Compliance Metric: Harper (IQVIA – defendant labelers; 1997-2006, 2008-2017)**

*Percentages are based on the number of total months the physician prescribed opioids from defendant labeler.*

Labeler	Common Sense	McKesson 8,000	Double National	Triple National	Any Flag
Endo	46.7	24.6	98.8	94.6	98.8
Johnson & Johnson	-	-	-	-	-
Mallinckrodt	54.5	26.3	98.7	95.5	98.7
Purdue	40.4	24.7	100.0	99.4	100.0
Teva	53.5	23.8	98.3	90.7	98.8

8. Flagged Prescriber 6: Dr. Syed Jawed Akhtar-Zaidi

108. Located at 34055 Solon Road in Solon, OH, Dr. Syed Jawed Akhtar-Zaidi was another prescriber in the IQVIA data who tripped all IQVIA compliance metrics. The following section describes how Zaidi was flagged and provides a profile of his prescribing patterns, as well as any known relevant contact he had with labeler defendants.

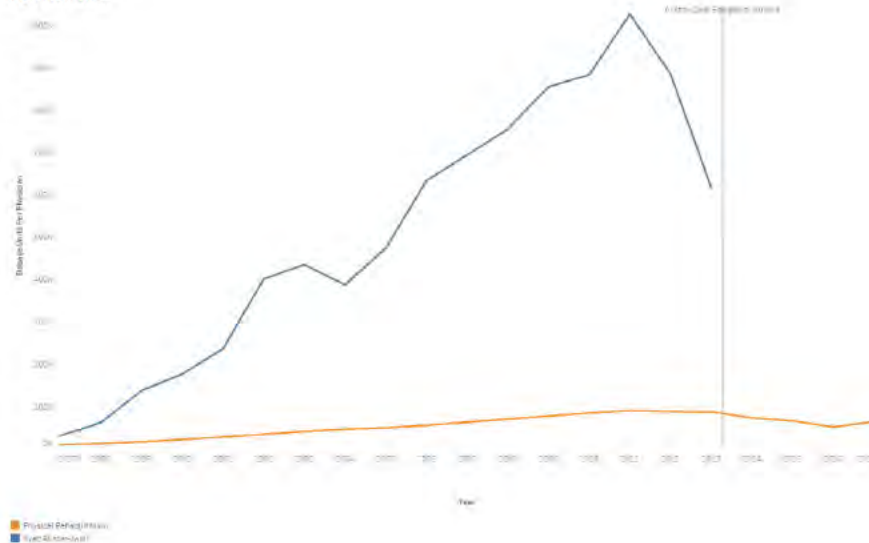
109. A physical medicine and rehabilitation specialist, Syed Jawed Akhtar-Zaidi operated Pain Management of Northern Ohio, a clinic located in Cuyahoga County. Of the variety of opioids Zaidi prescribed, his most prescribed drug was Mallinckrodt-labeled oxycodone 5mg. Purdue-labeled oxycodone 40mg accounted for about 15% of all MMEs he prescribed. Other rehab specialists in Ohio did not write more than 5% of prescriptions for any opioid stronger than 40 MMEs. Zaidi's prescriptions constantly climbed from 1997 to 2011, reaching a high peak of over 21,000 opioid prescriptions in 2011 – when the average prescription count per year among his specialty was less than 500 prescriptions.

110. Zaidi was indicted in 2014 by a federal grand jury on 46 separate counts that included charges of conspiracy to distribute controlled substances, distribution of controlled substances, health care fraud, and money laundering.<sup>127</sup> His license was revoked in 2015 by the State Medical Board of Ohio but Zaidi himself has been at large since 2014, when he fled to Pakistan before being arraigned. Below are tables that display the labeler and dosage for each drug that accounted for more than 5% of Zaidi's prescriptions. Also included is a chart visualizing the number of total prescriptions Zaidi wrote over time, shown in blue, compared to the statewide average among his specialty, shown in orange. The vertical line represents the year in which Zaidi was first flagged by Purdue, which is also the year he stopped prescribing.

<sup>127</sup> "Solon Doctor Indicted For Health Care Fraud And Illegally Distributing Prescription Painkillers." *The United States Department of Justice*, 12 Mar. 2015, [www.justice.gov/usao-ndoh/pr/solon-doctor-indicted-health-care-fraud-and-illegally-distributing-prescription](http://www.justice.gov/usao-ndoh/pr/solon-doctor-indicted-health-care-fraud-and-illegally-distributing-prescription).

**Figure 19 Physician Dosage Units Compared to Per Physician Specialty Average: Akhtar-Zaidi (IQVIA – all labelers; 1997-2006, 2008-2017)**

The lines below identifying the year in which the physician was identified as suspicious are the earliest reference I could find in produced documents.



**Table 24 Prescribing Overview by Labeler and Drug Dose: Akhtar-Zaidi (IQVIA – all labelers; 1997-2006, 2008-2017)**

Because of rounding, totals for the same prescriber may reflect slightly different values because of differences in the levels of underlying aggregation (i.e., drug-level vs. labeler-level). This table was filtered for opioids greater than 5% of prescriptions and sorted by percent of prescriptions.

Labeler	Drug and Dosage	Prescriptions	Prescriptions %	Dosage Units	Dosage Units %	MMEs	MMEs %
Mallinckrodt	Oxycodone 5mg	26,135	16.9	1,615,702	20.2	12,117,763	6.1
Teva	Oxycodone 5mg	9,638	6.2	551,222	6.9	4,134,162	2.1
Purdue	Oxycodone 40mg	9,457	6.1	502,213	6.3	30,132,768	15.1
Other	Other	109,715	69.7	5,319,111	64.9	153,664,230	75.2
All Labelers		154,945		7,988,248		200,048,923	

111. Most prescriptions that Zaidi wrote were labeled either by Mallinckrodt and Teva. However, Purdue- and Endo-labeled opioids accounted for more than half of the MMEs he prescribed. Internal Purdue documents indicated that the labeler called on him more than 280 times from 1996 (when OxyContin was launched) and 2013.<sup>128</sup> Additionally, Endo logs showed 362 calls between 2008 and 2013.<sup>129</sup> Zaidi was also listed in internal Mallinckrodt documentation as a top prescriber for high strengths of Exalgo and was targeted for “managed care opportunities.”<sup>130</sup> He was also contacted by Teva and Janssen as part of their marketing strategies for Actiq and Nucynta, respectively.<sup>131</sup> Despite contact with several leading labelers, Purdue was the only labeler to identify Zaidi as suspicious, although they did not identify him until the end of his

<sup>128</sup> PPLMDL0080000001, PPLMDL0020000001

<sup>129</sup> ENDO-OPIOID\_MDL-00673566

<sup>130</sup> MNK-T1\_0002111892

<sup>131</sup> TEVA\_MDL\_A\_02416207, JAN-MS-02756571, JAN-MS-02915712

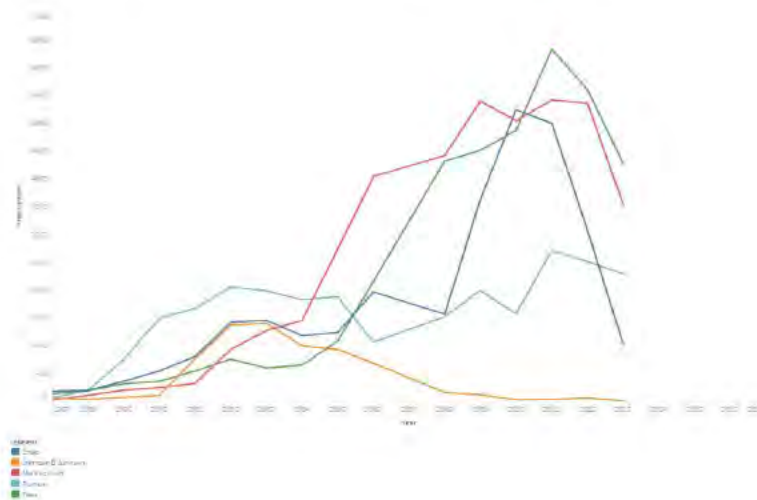
prescribing career.<sup>132</sup> Below is a table and chart that describe which defendants labeled the most opioids Zaidi prescribed, in total and over time.

**Table 25 Prescribing by Labeler: Akhtar-Zaidi**  
(IQVIA – all Labelers; 1997-2006, 2008-2017)

*Because of rounding, totals for the same prescriber may reflect slightly different values because of differences in the levels of underlying aggregation (i.e., drug-level vs. labeler-level). The table is sorted by percent of prescriptions.*

Labelers	Prescriptions	Prescription %	Dosage Units	Dosage Unit %	MMEs	MMEs %
<b>Mallinckrodt</b>	40,546	29.2	2,404,174	32.9	31,307,534	16.8
<b>Teva</b>	36,733	26.5	2,016,656	27.6	33,347,583	17.9
<b>Endo</b>	28,946	20.9	1,544,853	21.1	51,293,459	27.5
<b>Purdue</b>	25,628	18.5	1,280,161	17.5	69,953,754	37.5
<b>Johnson &amp; Johnson</b>	6,882	5.0	60,009	0.8	410,305	0.2
<b>Other Labelers</b>	19,466	12.3	814,206	10	19,649,376	9.5
<b>Total</b>	<b>158,201</b>		<b>8,120,059</b>		<b>205,962,011</b>	

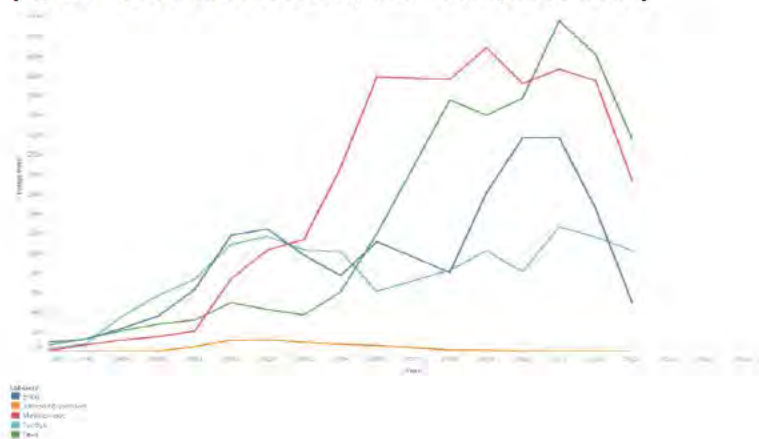
**Figure 20 Prescriptions by Labeler Over Time: Akhtar-Zaidi**  
(IQVIA – Defendant Labelers; 1997-2006, 2008-2017)



<sup>132</sup> PPLP004474184



**Figure 21 Dosage Units by Labeler Over Time: Akhtar-Zaidi (IQVIA – Defendant Labelers; 1997-2006, 2008-2017)**



112. Zaidi was captured by all prescriber compliance metrics, tripping the Double and Triple National Average metric in nearly all of the 16 years that he appeared in the IQVIA data for all labelers except Johnson & Johnson. The only compliance metric he did not trip was McKesson 8,000 for prescriptions of Johnson & Johnson products. Even compared to other highly flagged prescribers, Zaidi was flagged for an extraordinarily high number of months. For example, he still was identified by compliance metric he triggered the least (Common Sense) for 28% of the months he wrote Johnson & Johnson; 42% of months he wrote prescriptions for Purdue opioids; more than 60% of months he wrote Endo and Mallinckrodt opioid prescriptions; and nearly 70% of months he wrote Teva opioid prescriptions. Below is a table that displays the percentage of total months during which Zaidi was prescribing that was flagged by the application of the compliance metrics.

**Table 26 Percentage of Prescribing Months Flagged by Compliance Metric: Akhtar-Zaidi (IQVIA – defendant labelers; 1997-2006, 2008-2017)**

*Percentages are based on the number of total months the physician prescribed opioids from defendant labeler.*

Labeler	Common Sense	McKesson 8,000	Double National	Triple National	Any Flag
Endo	63.4	70.2	99.5	99.5	99.5
Johnson & Johnson	27.6	-	82.3	79.6	83.4
Mallinckrodt	61.6	70.5	94.7	94.7	94.7
Purdue	41.9	70.2	99.5	99.5	99.5
Teva	70.8	69.3	94.8	92.2	95.3

## 9. Small Labeler Impact

113. I was directed by counsel to determine the impact on Summit and Cuyahoga counties' opioid prescriptions if Janssen had identified and reported prescribers to authorities. The hypothetical scenario considers the effect on prescription totals that even labelers with small market shares could have had if they flagged and reported suspicious prescribers. Had even a small labeler like Janssen used an adequate SOMS methodology, it could have still heavily influenced the amount of opioid prescriptions flooding the counties.

114. I first assume that Janssen flagged the prescribers appropriately identified in the IQVIA metrics and that Janssen subsequently reported those suspicious prescribers to the DEA or other regulatory authorities and stopped supplies to the doctors. This ultimately assesses how such diligence by Janssen would have impacted the number of opioids in circulation if the flagged prescribers were stopped from writing prescriptions at the earliest indication of irregular behavior. I have given Janssen benefit of the doubt that they only would have flagged doctors starting on whichever date was later: either a prescriber's earliest flagging date or the issue date of a prescriber's first prescription in their sixth month of prescribing Janssen's products. I chose this method despite the fact that Janssen (like other labelers) was using IQVIA data for their competitors' drugs as well as their own and would have been aware of doctors that were not Janssen prescribers.

115. Extrapolated to all flagged prescribers, even a small labeler like Janssen could have had a curtailing effect on the excess of opioids prescribed in the counties. Problematic prescribers would have had to stop prescribing opioids made by all labelers, not only those made by the labeler who reported them. I used three metrics in this methodology: Double National Average, Triple National Average, and Common Sense. Because the McKesson 8,000 dosage units metric applies to only oxycodone and hydrocodone products, this metric is not applicable to Janssen.

116. The tables below provide an overview of the prescriptions, dosage units, and MMEs that could have been stopped if Janssen had applied three of the IQVIA metrics to Summit and Cuyahoga doctors and reported and stopped the supply to each flagged physician. As shown, Janssen could have stopped up to 15% of all prescriptions written in Summit and Cuyahoga counties between 1997 and 2017, depending on which compliance metric it used. By use of the Double National Average metric alone, Janssen could have stopped around 14% of transactions in the counties. Similar percentages of prescriptions could have been stopped according to the other compliance metrics. The tables further highlight the number of suspicious doctors who could have been potentially identified. Included with each table is a corresponding graph that visualizes the number of actual prescriptions, shown in orange, compared to the number of prescriptions that could have been potentially stopped, shown in blue, had Janssen employed the methodology.

**Table 27 Double National Average Compliance Metric Cuyahoga and Summit Counties  
(IQVIA – Defendant Labelers; 1997-2006, 2008-2017)**

County	Potentially Stopped Prescribers	Potentially Stopped Prescriptions	Potentially Stopped Doses	Potentially Stopped MMEs	Total Prescribers	Total Prescriptions	Total Doses	Total MMEs	Potentially Stopped % of All Prescribers	Potentially Stopped % of All Prescriptions	Potentially Stopped % of all Doses	Potentially Stopped % of all MMEs
SUMMIT	209	1,153,897	86,987,508	1,048,282,410	3,661	7,117,178	381,044,786	4,312,500,216	5.7	16.2	22.8	24.3
CUYAHOGA	582	2,463,252	188,916,955	2,584,988,750	14,114	17,387,237	955,994,343	10,903,362,756	4.1	14.2	19.8	23.7

**Table 28 Triple National Average Compliance Metric Cuyahoga and Summit Counties  
(IQVIA – Defendant Labelers; 1997-2006, 2008-2017)**

County	Potentially Stopped Prescribers	Potentially Stopped Prescriptions	Potentially Stopped Doses	Potentially Stopped MMEs	Total Prescribers	Total Prescriptions	Total Doses	Total MMEs	Potentially Stopped % of All Prescribers	Potentially Stopped % of All Prescriptions	Potentially Stopped % of all Doses	Potentially Stopped % of all MMEs
SUMMIT	203	1,149,122	86,721,483	1,045,486,577	3,661	7,117,178	381,044,786	4,312,500,216	5.5	16.2	22.8	24.2
CUYAHOGA	543	2,436,374	187,329,408	2,568,639,918	14,114	17,387,237	955,994,343	10,903,362,756	3.9	14.0	19.6	23.6

**Table 29 Common Sense Compliance Metric Cuyahoga and Summit Counties  
(IQVIA – Defendant Labelers; 1997-2006, 2008-2017)**

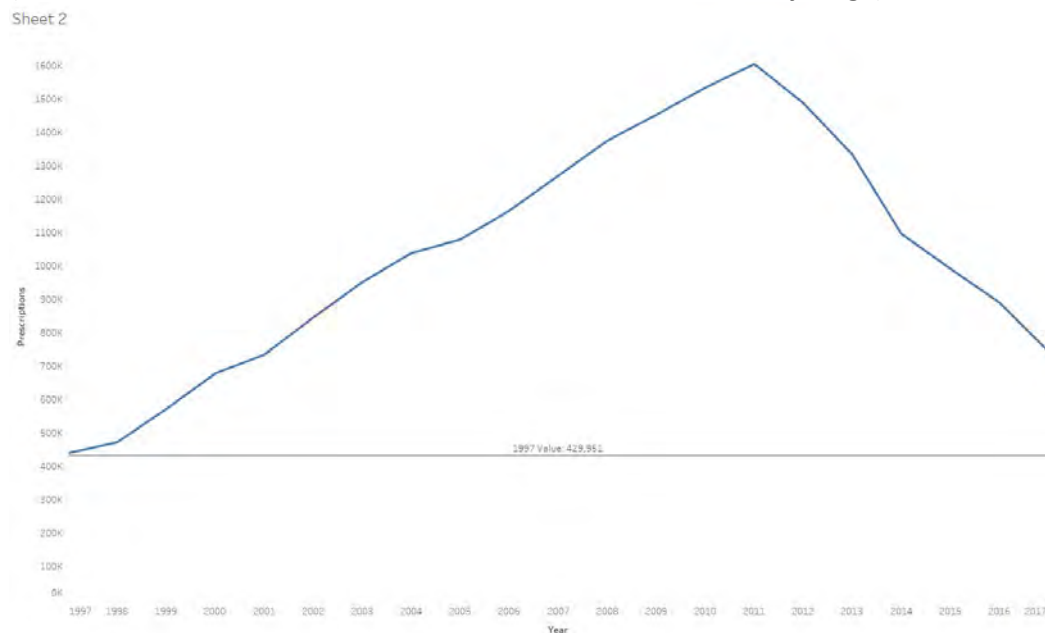
County	Potentially Stopped Prescribers	Potentially Stopped Prescriptions	Potentially Stopped Doses	Potentially Stopped MMEs	Total Prescribers	Total Prescriptions	Total Doses	Total MMEs	Potentially Stopped % of All Prescribers	Potentially Stopped % of All Prescriptions	Potentially Stopped % of all Doses	Potentially Stopped % of all MMEs
SUMMIT	210	1,153,711	86,959,871	1,048,197,137	3,661	7,117,178	381,044,786	4,312,500,216	5.7	16.2	22.8	24.3
CUYAHOGA	598	2,459,981	188,463,013	2,581,955,729	14,114	17,387,237	955,994,343	10,903,362,756	4.2	14.2	19.7	23.7



## 10. Baseline Year Analysis

117. I was asked by counsel to determine what would have been flagged by the methodology if prescribing thresholds were set to a baseline year instead of operating as self-referential averages. Given the fact that opioid prescriptions rose significantly nationwide from 1997 through 2011, 1997 was selected as the baseline year. This prevented thresholds from increasing alongside the rising volume of opioids and treated each prescriber of defendant-labeled opioids as though total prescriptions, dosage units, and MMEs as prescribed in 1997 were appropriate baseline values. Below is a graph that displays how the total number of prescriptions rose over the years in IQVIA data as compared to the value of prescriptions in 1997.

**Figure 22 Total Prescriptions Over Time Compared to 1997 Prescription Total (IQVIA – Defendant Labelers; 1997-2006, 2008-2017 Summit, Cuyahoga)**



118. The 1997 benchmark was applied to physicians for three compliance metrics applied to IQVIA data: Double National Average, Triple National Average, and Common Sense. This analysis was only completed using IQVIA data, as chargeback data had varying production dates by defendant and would have yielded uneven results and the ARCOS data started much later (2006), after the volume of opioids nationwide had already considerably risen.

119. To benchmark the Double National Average compliance metric to 1997, I calculated the average monthly prescriptions, prescribed dosage units, and prescribed MMEs for each prescriber specialty and drug code in 1997. Prescribers were flagged if the volume of their prescriptions, prescribed dosage units, or prescribed MMEs were more than twice the 1997 monthly average for their cohort. This metric was only applied to prescriber specialties and drug codes that appear in the IQVIA data for 1997.

120. I benchmarked the Triple National Average compliance metric to 1997 in the same way, and flagged prescribers if their prescriptions, dosage units, or MMEs were over three times the monthly average for their cohort in 1997.

121. To benchmark the Common Sense compliance metric to 1997, a prescriber was flagged if his or her monthly prescriptions, prescribed dosage units, or prescribed MMEs were higher than his or her maximum monthly prescribing for that drug code in 1997. Prescribers were only flagged if they appear in the IQVIA database and prescribed the relevant drug code in 1997. Because this compliance metric is benchmarked to the prescriber's highest monthly rates of prescribing in 1997, the metric was only triggered starting in 1998.

122. Applying the Common Sense metric against the 1997 baseline yielded almost 200 million dosage units above what was captured by the moving average for every year analyzed. Over 125 million more dosage units were captured by the Double National and almost 100 million more dosage units were captured by the Triple National compliance metric when set to 1997 than when the metric was allowed to adjust over time.

123. The tables below analyzes the flagged physicians, prescriptions, dosage units, and MMEs that would have been captured relative to 1997 values instead of year over year, updating averages. These values were attributed to each compliance metric as well as to labelers. Note that Common Sense did not trigger any compliance metrics in 1997 since the metric was based on 1997 highest values and the year cannot exceed its own highest value.

**Table 30 Comparison of Flagged Physicians Using Baseline Year Methodology (IQVIA – Defendant Labelers; 1997-2006, 2008-2017 Summit, Cuyahoga)**

<b>Metric</b>	<b>Year Over Year</b>	<b>Baseline Year</b>	<b>Difference</b>
Common Sense	13,375	4,639	8,736
Double National Avg	5,526	6,683	1,157
Triple National Avg	7,441	8,439	998

**Table 31 Comparison of Flagged Prescriptions Using Baseline Year Methodology (IQVIA – Defendant Labelers; 1997-2006, 2008-2017 Summit, Cuyahoga)**

<b>Metric</b>	<b>Year Over Year</b>	<b>Baseline Year</b>	<b>Difference</b>
Common Sense	6,478,063	9,852,005	3,373,942
Double National Avg	10,677,069	12,667,164	1,990,095
Triple National Avg	13,240,306	14,775,493	1,535,187

**Table 32 Comparison of Flagged Dosage Units Using Baseline Year Methodology (IQVIA – Defendant Labelers; 1997-2006, 2008-2017 Summit, Cuyahoga)**

<b>Metric</b>	<b>Year Over Year</b>	<b>Baseline Year</b>	<b>Difference</b>
Common Sense	346,664,806	539,609,284	192,944,478
Double National Avg	628,269,023	755,063,997	126,794,973
Triple National Avg	752,860,314	847,079,164	94,218,849

**Table 33 Comparison of Flagged MMEs Using Baseline Year Methodology (IQVIA – Defendant Labelers; 1997-2006, 2008-2017 Summit, Cuyahoga)**

Metric	Year Over Year	Baseline Year	Difference
Common Sense	4,173,047,316	6,381,800,878	2,208,753,562
Double National Avg	8,095,048,941	9,628,437,451	1,533,388,510
Triple National Avg	9,323,502,171	10,427,967,814	1,104,465,643

## L. Part Two: Manufacturer to Pharmacy Analysis

124. This section examines patterns of transaction between labelers and downstream customers through labeler defendant produced chargeback and 867 data. The pharmaceutical industry uses chargebacks to protect distributors against profit loss.<sup>133</sup> Such loss may occur if the price at which the distributor sells the drug product is lower than the price at which the drug was purchased from the labeler. In these cases, the distributor submits a chargeback request with information about the distributor, where the purchase was shipped, what entity purchased it, and for what price. Because the request for reimbursement must include all sales data, chargebacks allow the labeler to trace their drugs through the distribution chain; Labelers would only be capable of identifying suspicious purchases regarding sales that resulted in chargeback requests.

125. Below is a table that groups subsidiaries and their parent companies and indicates the scope of their 867 or chargeback data (i.e., what dates the production covered and a high-level summary of the data it contained). For some companies, the chargeback data represented a large percentage of all orders. For example, for Mallinckrodt between 2009 and 2012, 96% of all oxycodone 15 orders and 98% of all oxycodone 30 orders were subject to chargeback requests, and hence would be in the chargeback database.<sup>134</sup> In 2017, Teva stated that about 51% of controlled substance transactions resulted in a chargeback.<sup>135</sup> Even with only partial coverage of downstream customer purchases, chargebacks were a useful tool in monitoring suspicious transactions at the pharmacy level from a manufacturer's perspective, as evidenced in how the labeler defendants themselves were aggregating and monitoring chargeback data. The impact of partial coverage of chargeback data is only that fewer transactions could be monitored for suspicious activity; thus, more complete data would not change the analysis of existing suspicious orders but might identify additional orders. The following tables demonstrate my findings regarding whether labelers used their own chargeback data to identify suspicious buyers as part of a SOM program, to the best of my knowledge. This reflects chargeback data that I was able to locate among produced data after my best efforts to verify the full scope of chargeback data defendants had and/or produced. I reserve the right to modify or supplement this report in the event that additional data is produced or identified.

<sup>133</sup> MNK-T1 0000280621

<sup>134</sup> Gillies 30(b)(6) Transcript at 269:6-274:2, 271:3-274:2 and Gillies 30(b)(6) Exhibit 30 (MNK-T1\_0008434954).

<sup>135</sup> TEVA\_MDL\_A\_02476562

**Table 34 Chargeback/867 Data Quality and Source by Defendant Labeler***Note: Reflects data after processing as described in the methodology section of this report*

Parent Company	Labeler Name	Minimum Year	Maximum Year	# Buyers (Based on ID No)	# NDCS	# Chargebacks
INSYS	INSYS	n/a	n/a	n/a	n/a	n/a
	Endo	1998	2018	76,390	98	7,519,723
Endo	Par	2010	2018	78,667	95	10,865,674
	Qualitest	2007	2016	93,703	144	21,698,701
Mallinckrodt	Mallinckrodt	1998	2017	122,517	146	81,892,954
Purdue	Purdue <sup>136</sup>	2009	2018	65,636	63	16,026,336
	Actavis	2001	2016	96,174	158	54,224,394
Teva	Allergan	2002	2018	2,237	32	13,986
	Teva	2011	2018	76,079	105	15,300,086
Johnson & Johnson	Janssen	2009	2018	77	15	1,958

**Table 35 Use of Chargeback Data for Compliance**

Parent Company	Labeler Name	Produced Chargeback Data	Had SOM Program	Used Chargeback in SOM Program
INSYS	INSYS	Yes	No	No
	Endo	Yes	No	No <sup>137</sup>
Endo	Par	Yes	Yes	No <sup>138</sup>
	Qualitest	Yes	Yes	No <sup>139</sup>
Mallinckrodt	Mallinckrodt	Yes	Yes	Yes <sup>140</sup>
Purdue	Purdue	Yes	Yes	Yes <sup>141</sup>
	Actavis	Yes	Yes	Yes <sup>142</sup>
Teva	Teva	Yes	Yes	Yes <sup>143</sup>
	Allergan	Yes	Yes	Yes <sup>144</sup>
Johnson & Johnson	Janssen	Yes	Yes <sup>145</sup>	No

## 1. Results of Compliance Metric Application

126. The following tables summarize the overall results of applying compliance metrics to labeler defendant chargeback data. Compliance metrics were applied by month in all cases except Actavis 125% Order, which was applied order by order. As noted above, every month (or every transaction in the case of Actavis), metrics were re-applied so that a buyer flagged for the previous

<sup>136</sup> The data produced by Purdue is 867 (point-of-sale) data – not chargeback data.

<sup>137</sup> L. Walker Tr. 190:1-5

<sup>138</sup> Par's SOMS program was deficient as of 2015. PAR\_OPIOID\_MDL\_0001024034, PAR\_OPIOID\_MDL\_0001596366. After it was acquired by Endo, it absorbed the Qualitest business, and adopted the Qualitest system PAR\_OPIOID\_MDL\_0001596366.

<sup>139</sup> Qualitest did not use chargeback data until after their March 2013 meeting with DEA. PAR\_OPIOID\_MDL\_0001647888, T. Norton Tr. 71:12-73:5, E. Brantley Tr. 472:9-11.

<sup>140</sup> It appears that Mallinckrodt first began using chargeback data in 2010 in response to a demand from DEA that it needed to know its customer's customer. See MNK-T1\_000269747 (July 21, 2010 Email from K. Harper to T. Berry). Mallinckrodt did not formally incorporate chargeback data into its SOM program until early 2011. MNK-T1\_000264214 (Global Controlled Substance Compliance Procedure, Jan. 4, 2011).

<sup>141</sup> For 867 data: PPLPC023000971890, PPLP004192884, PPLP004192931, PPLP004397418, PPLPC0320003748086

<sup>142</sup> Acquired\_Actavis\_00488498, Acquired\_Actavis\_00945856, TEVA\_MDL\_A\_01037228

<sup>143</sup> TEVA\_MDL\_A\_02476562, TEVA\_MDL\_A\_01060005, TEVA\_MDL\_A\_03479111. Though Teva admits it always had access to chargeback and 867 data during the period it sold opioids, it was only approximately in 2015 it started using chargeback data and in 2017 it started using ValueCentric 867 data. [11/28/18 Tomkiewicz Dep. pp. 379-389; Tomkiewicz Dep p. 477:14-2; Teva also uses ValueCentric data as set forth below. TEVA\_MDL\_A\_01453994 (7/9/12 McGinn email re 867 data); TEVA\_MDL\_A\_01471221 (5/18/18 McGinn email re 867 data); 12/14/18 McGinn Depo Exh. 13, PPT, Slide 8]

<sup>144</sup> The first Allergan SOM policy calling for the inspection of chargeback data is dated May 2016. TEVA\_MDL\_A\_01037228 at -233. Allergan corporate representative said it abandoned its SOM system in three months later in August 2016 when it ceased being a DEA Registrant. See Deposition of Mary Woods, 01-09-2019 at 12-20.

<sup>145</sup> JAN-MS-00454958

month or transaction did not remain flagged in the following month or transaction. The alternative would be to keep the buyer flagged until additional diligence was performed, which would have been equally reasonable. Lacking information about whether diligence was performed by defendant labelers, I gave them the benefit of assuming diligence. Maintaining the metrics absent evidence of adequate due diligence would have resulted in substantially higher numbers of flagged transactions. Note that distributor information was only available insofar as labeler defendant productions contained information on the reporter intermediary in the chargeback. As shown in the charts below, this resulted in null values for some labelers. Below are tables that display these trends with more granularity, breaking down compliance metrics by buyer and dosage unit totals both per labeler and per metric.

**Table 36 Flagged Chargeback Transactions by Compliance Metric  
(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**

Metric Type	Flagged Buyers	% of All Buyers	Flagged Chargebacks	% of All Chargebacks	Flagged Dosage Units	% of All Dosage Units	Total Months Flagged
Double National Average	817	63.4	472,116	44.1	286,836,011	58.3	250
Triple National Average	788	61.1	307,208	28.7	207,692,478	42.2	246
McKesson: 8,000 Rule	293	22.7	208,652	19.5	186,085,340	37.8	185
Masters: Common Sense	1,013	78.6	323,455	30.2	152,723,817	31.0	244
Qualitest (Endo): 30,000 Rule	21	1.6	4,475	0.4	5,557,600	1.1	85
Mallinckrodt: Rolling Average (Double)	821	63.7	162,474	15.2	72,259,921	14.7	231
Mallinckrodt: Rolling Average (Triple)	730	56.6	65,686	6.1	31,022,783	6.3	225
Actavis (Teva): 125% Order Average	946	73.4	624,965	58.4	327,685,770	66.6	246
Teva: 3 SD Above Six Month Mean	765	59.4	122,294	11.4	63,069,827	12.8	244
Multiple Distributors	295	22.9	23,946	2.2	13,952,780	2.8	174
Any Flag	1,065	82.6	816,892	76.3	421,971,346	85.8	250



**Table 38 Number of Flagged Buyers Attributed to Each Labeler  
(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**

Labeler	Total Buyers	Double National	Triple National	McKesson: 8,000	Masters: Common Sense	Qualitest: 30K	Mallinckrodt: Rolling Average (2x)	Mallinckrodt: Rolling Average (3x)	Actavis: 125% Order	Teva: 3 Standard Deviations	Multiple Distributor	Any Flag
Actavis	487	313	375	175	447	14	393	373	423	372	0	449
Allergan	11	1	0	0	1	0	0	0	1	0	0	2
Endo	439	309	282	19	368	0	298	246	326	243	0	380
Janssen	12	4	3	0	7	0	5	3	5	0	0	7
Mallinckrodt	678	438	455	177	564	10	488	446	557	484	294	595
Par	382	219	234	59	324	0	240	200	308	197	0	333
Purdue	272	117	142	18	230	0	190	128	229	186	49	242
Qualitest	432	284	315	105	360	2	334	317	348	289	0	368
Teva	379	141	149	46	322	0	202	118	291	186	2	330



**Table 39 Number of Flagged Dosage Units Attributed to Each Labeler  
(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**

Labeler	Double National	Triple National	McKesson: 8,000	Masters: Common Sense	Qualitest: 30K	Mallinckrodt: Rolling Average (2x)	Mallinckrodt: Rolling Average (3x)	Actavis: 125% Order	Teva: 3 Standard Deviations	Multiple Distributor	Any Flag
Actavis	61,127,415	45,000,955	54,565,000	34,822,290	1,355,000	19,146,625	9,144,240	74,651,735	17,207,540		95,358,545
Allergan	600			200				200			1,000
Endo	10,706,720	8,230,400	1,551,700	5,184,120		3,252,400	1,322,120	8,215,880	2,267,620		13,299,220
Janssen	4,880	2,120		7,800		4,220	1,400	5,300			9,500
Mallinckrodt	147,079,776	108,631,163	85,098,270	76,288,227	4,081,140	30,893,596	11,338,368	169,172,105	25,389,882	13,647,855	208,688,966
Par	13,403,625	8,051,330	6,287,800	6,490,650		1,991,090	945,265	11,382,300	1,649,820		19,733,795
Purdue	6,001,340	4,242,420	1,171,880	3,016,420		1,396,620	717,200	6,228,100	1,800,420	300,300	8,414,560
Qualitest	26,925,860	19,028,550	15,233,090	17,560,590	121,460	14,385,210	7,267,430	28,061,030	9,224,090		40,565,660
Teva	21,585,795	14,505,540	22,177,600	9,353,520		1,190,160	286,760	29,969,120	5,530,455	4,625	35,900,100

**Table 40 Number of Flagged Buyers Attributed to Buyer Business Activity  
(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**

Buyer Type	Total Buyers	Double National	Triple National	McKesson: 8,000	Masters: Common Sense	Qualitest: 30K	Mallinckrodt: Rolling Average (2x)	Mallinckrodt: Rolling Average (3x)	Actavis: 125% Order	Teva: 3 Standard Deviations	Multiple Distributor	Any Flag
Chain Pharmacy	710	521	508	191	609	8	532	488	575	495	202	627
Retail Pharmacy	523	285	271	100	385	13	285	240	356	268	87	411
Practitioner	57	11	9	2	19	0	4	2	15	2	6	27

**Table 41 Number of Flagged Dosage Units Attributed to Buyer Business Activity  
(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**

Buyer Type	Double National	Triple National	McKesson: 8,000	Masters: Common Sense	Qualitest: 30K	Mallinckrodt: Rolling Average (2x)	Mallinckrodt: Rolling Average (3x)	Actavis: 125% Order	Teva: 3 Standard Deviations	Multiple Distributor	Any Flag
Chain Pharmacy	184,661,698	125,678,895	116,493,786	101,064,539	832,948	48,119,246	21,124,789	224,080,977	39,381,616	5,536,537	284,534,342
Retail Pharmacy	101,965,613	81,857,283	69,533,154	51,543,718	4,724,652	24,088,075	9,884,394	103,453,093	23,672,511	8,410,643	137,144,444
Practitioner	208,700	156,300	58,400	115,560		52,600	13,600	151,700	15,700	5,600	292,560

127. The section that follows analyzes suspicious pharmacies about which labelers could have known and reported, given that all labeler defendants had their chargeback data. Therefore, each labeler included in this analysis could have been aware of all purchasing activity flagged by this methodology. All labelers were subject to every compliance metric but were flagged only for their own transactions. Note that calculations were not made on a per capita basis. Nonetheless, every example pharmacy was found to purchase at a significantly higher rate than the median pharmacy in Summit and Cuyahoga counties. These abbreviated case studies on individual pharmacies is not meant as a list of every suspicious pharmacy in Cuyahoga and Summit but intended to provide examples of the data that labelers had that clearly revealed suspicious pharmacies who dispensed millions of pills into Cuyahoga and Summit counties.

2. Flagged Pharmacy 1: [REDACTED]

128. Located at [REDACTED] in Cleveland, [REDACTED] was flagged many times by the methodology. The following section describes how [REDACTED] was flagged and provides a profile of the pharmacy's transaction patterns with the labeler defendants. Totals were calculated by ARCOS and then by chargeback data to provide as complete a picture as possible of pharmacy purchasing patterns. The section ends with descriptions of how the flagging methodology was applied to [REDACTED]. To the best of my knowledge, [REDACTED] was the only pharmacy in either Summit County or Cuyahoga County that was identified by any defendant labeler (Mallinckrodt) as potentially suspicious.<sup>146</sup>

129. A single location of a pharmacy chain, [REDACTED] purchased enough opioids to supply Cuyahoga County with almost 2 million dosage units in just eight years, according to ARCOS data. Most opioids purchased by [REDACTED] were labeled by Mallinckrodt, which labeled almost three-quarters of all dosage units that the pharmacy purchased. Mallinckrodt alone labeled more products that [REDACTED]s purchased than all other defendant labelers combined. The other two leading drugs that [REDACTED]'s purchased were high dose Purdue products. Mallinckrodt was the only defendant labeler to identify the pharmacy as suspicious, placing them on a 2016 "cut off pharmacy" list.<sup>147</sup> Below are tables that display the drug, dosage, and labeler combinations that [REDACTED] purchased for more than 5% of transactions, dosage units, and MMEs. Also included is a table and graph that display this information per labeler, both in total and over time.

<sup>146</sup> MNK-T1\_0001315847

<sup>147</sup> MNK-T1\_0001315847

**Table 42 Transactions by Labeler and Drug and Dosage:** [REDACTED]  
(ARCOS; 2006 - 2014)

Table sorted by percent of dosage units.

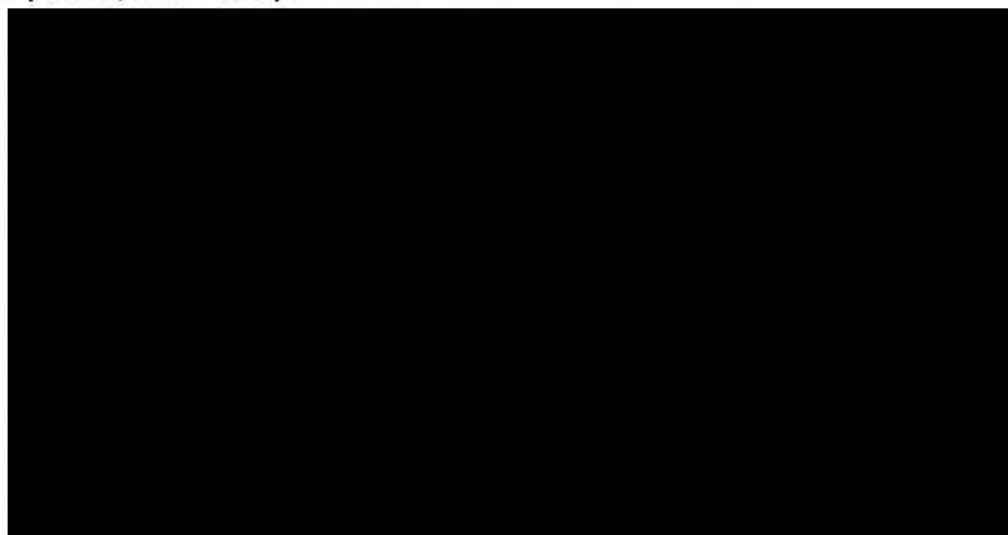
Labeler	Drug and Dosage	Pharmacy Total Transactions	% Pharmacy Transactions	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Mallinckrodt	Oxycodone 5mg	559	9.3	468,500	25.0	3,150,077	10.6
Mallinckrodt	Hydrocodone 5mg	501	8.3	241,700	12.9	731,626	2.5
Mallinckrodt	Hydrocodone 7.5mg	515	8.6	217,400	11.6	987,105	3.3
Mallinckrodt	Hydrocodone 10mg	989	16.5	194,320	10.4	1,176,413	4.0
Purdue	Oxycodone 40mg	316	5.3	87,900	4.7	4,728,141	15.9
Purdue	Oxycodone 80mg	294	4.9	72,200	3.9	7,767,276	26.2
[REDACTED]							
<b>Total</b>	<b>All</b>	<b>5,863</b>		<b>1,877,225</b>		<b>29,642,678</b>	

**Table 43 Transactions by Labeler:** [REDACTED]  
(ARCOS; 2006-2014)

Table sorted by percent of dosage units.

Labeler	Pharmacy Total Transactions	% Pharmacy Total Transactions	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Mallinckrodt	3,237	61.7	1,297,230	73.4	8,374,043	30.7
Purdue	964	18.4	214,800	12.2	14,217,406	52.1
[REDACTED]						
Teva	442	8.4	74,450	4.2	1,754,424	6.4
Johnson & Johnson	92	1.8	4,935	0.3	569,000	2.1
<b>Total</b>	<b>5,243</b>		<b>1,767,055</b>		<b>27,294,523</b>	

**Figure 23 Dosage Units by Labeler Over Time:** [REDACTED]  
(ARCOS; 2006 - 2014)



Labeler Name Grouped by Year  
 ■ Endo  
 ■ Johnson & Johnson  
 ■ Mallinckrodt  
 ■ Purdue  
 ■ Teva

130. The number of Mallinckrodt chargebacks that pertained to [REDACTED] were significantly higher than chargebacks for other defendant labelers. Mallinckrodt chargebacks increased substantially with every year from 2002 to 2009, when they peaked before rapidly declining and plateauing. As Mallinckrodt chargebacks leveled off, Qualitest chargebacks involving [REDACTED] spiked. Both ARCOS and chargeback data showed the same top three drugs as the most frequently purchased by [REDACTED]: hydrocodone 10mg and 7.5mg, and oxycodone 5mg. Market shares should not be compared between ARCOS and the chargeback data because labeler defendants produced differing time frames of chargeback data. Below is a table that breaks down top opioid drugs and dosages by chargebacks, dosage units, and MMEs in opioid chargebacks involving [REDACTED]. Also included is a table and chart that display labeler market share.

**Table 44 Transactions by Labeler and Drug and Dosage: [REDACTED]**  
(Chargebacks – Defendant Labelers; Varies Between 1998-2018)

Table sorted by percent of chargebacks.

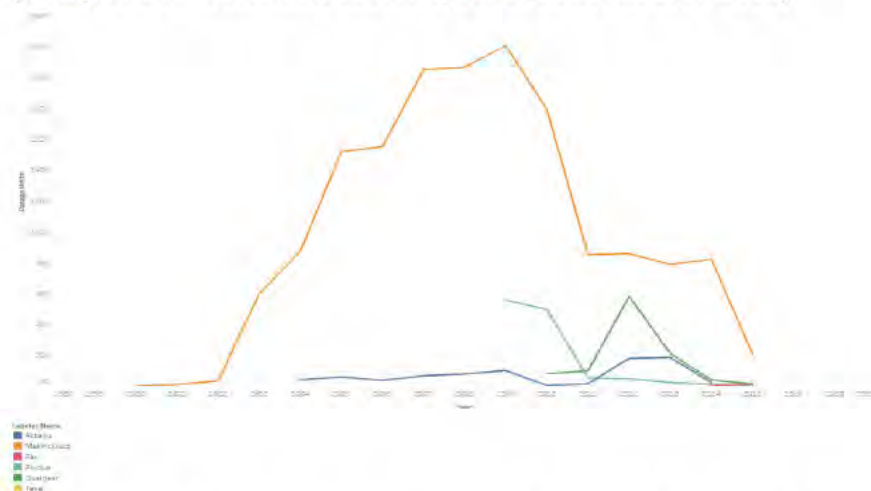
Labeler	Drug and Dosage	Pharmacy Total Chargebacks	% Pharmacy Total Chargebacks	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Mallinckrodt	Oxycodone 5mg	665	13.6	550,300	28.6	4,127,250	16.2
Mallinckrodt	Hydrocodone 5mg	643	13.2	341,300	17.7	1,706,500	6.7
Mallinckrodt	Hydrocodone 7mg	672	13.8	318,532	16.5	2,388,990	9.4
Mallinckrodt	Hydrocodone 10mg	1,293	26.5	257,800	13.4	2,578,000	10.1
Mallinckrodt	Oxycodone 10mg	200	4.1	89,600	4.7	1,344,000	5.3
Purdue	Oxycodone 80mg	142	2.9	48,900	2.5	5,868,000	23.0
Purdue	Oxycodone 40mg	138	2.8	43,700	2.3	2,622,000	10.3
Other Labelers	Other	1,099	22.5	275,175	14.3	4,833,723	19.0
<b>Total</b>		<b>4,852</b>		<b>1,925,307</b>		<b>25,468,463</b>	

**Table 45 Transactions by Labeler: [REDACTED]**  
(Chargebacks – Defendant Labelers; Varies Between 1998-2018)

Labeler	Pharmacy Total Chargebacks	% Pharmacy Total Chargebacks	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Actavis	374	7.7	78,555	4.1	1,077,521	4.2
Mallinckrodt	3,805	77.9	1,623,042	84.3	13,540,215	53.1
Par	4	0.1	1,500	0.1	10,750	0
Purdue	473	9.7	119,100	6.2	9,573,000	37.6
Qualitest	213	4.4	102,240	5.3	1,263,897	5.0
Teva	17	0.4	870	0.1	19,236	0.1
<b>Total</b>	<b>4,886</b>		<b>1,925,307</b>		<b>25,484,619</b>	



**Figure 24 Dosage Units by Labeler Over Time** [REDACTED]  
**(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**



131. [REDACTED] was identified as suspicious by Cardinal Health as well as by the methodology used in this report. In November 2014, Cardinal Health noted that [REDACTED] had been over its ordering threshold limit more than 80% of the time they ordered from the distributor.<sup>148</sup> Marc's triggered nine of the ten metrics involved in this methodology. Below is a table that displays the percentage of total months of chargebacks involving [REDACTED] that were flagged by application of compliance metrics. Also included in the table below is a column that indicates the percentage of months that the pharmacy tripped at least one compliance metric.

**Table 46 Months Flagged by Labeler:** [REDACTED]  
**(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**

*Percentage of months were calculated off a labeler's own chargeback data.*

Labeler	Double National	Triple National	McKesson: 8,000	Masters: Common Sense	Qualitest: 30,000	Mallinckrodt: Rolling Average (2x)	Mallinckrodt: Rolling Average (3x)	Actavis: 125% Order	Multiple Distributor	Teva: 3 Standard Deviations	Any Flag
Actavis	2.8	8.41	0	26.17	0	15.89	10.28	34.58	0	6.54	46.73
Mallinckrodt	74.84	57.23	36.48	43.4	0	16.98	6.29	86.79	3.14	13.21	91.82
Par	0	0	0	0	0	0	0	0	0	0	0
Purdue	28.33	25	6.67	10	0	0	0	28.33	1.67	1.67	48.33
Qualitest	4.55	4.55	0	22.73	0	4.55	4.55	29.55	0	13.64	47.73
Teva	0	0	0	18.18	0	0	0	18.18	0	0	27.27

### 3. Flagged Pharmacy 2: [REDACTED]

132. Located at [REDACTED] in Cleveland, this [REDACTED] was another pharmacy also could have triggered labelers' SOM systems. The following section describes how this [REDACTED] was flagged and provides a profile of the pharmacy's transaction patterns. Totals were calculated by ARCOS and then by chargeback data to provide as complete a picture as possible of pharmacy purchasing patterns. The section ends with descriptions of how the compliance metrics were applied to [REDACTED]

<sup>148</sup> CAH\_MDL2804\_00005624



133. According to ARCOS, Mallinckrodt labeled about half of all dosage units shipped to the pharmacy. However, Purdue-labeled oxycodone 80mg made up nearly one-third of all MMEs shipped to this [REDACTED]. Purchases of Mallinckrodt-labeled opioids increased with every year from 2006 until 2010, and purchases of Purdue opioid products increased at their greatest rate from 2007 to 2009 before declining. Mallinckrodt was the only defendant labeler to identify the pharmacy as suspicious, placing them on a 2016 “cut off pharmacy” list.<sup>149</sup> Below are tables that display the drug, dosage, and labeler combinations that [REDACTED] purchased that reflect more than 5% of transactions, dosage units, and MMEs. Also included is a table and graph that display this information per labeler, both in total and over time.

**Table 47 Transactions by Labeler and Drug and Dosage:** [REDACTED]  
(ARCOS; 2006 - 2014)

*Table sorted by percent of dosage units.*

Labeler	Drug and Dosage	Pharmacy Total Transactions	% Pharmacy Total Transactions	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Mallinckrodt	Oxycodone 5mg	[REDACTED]					
Mallinckrodt	Hydrocodone 5mg						
Teva	Codeine 30mg						
Purdue	Oxycodone 80mg						
Purdue	Oxycodone 40mg						
Teva	Codeine 60mg						
Total		[REDACTED]					

**Table 48 Transactions by Labeler:** [REDACTED]  
(ARCOS; 2006-2014)

Labeler	Pharmacy Total Transactions	% Pharmacy Total Transactions	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Mallinckrodt	[REDACTED]					
Teva						
Purdue						
[REDACTED]						
Johnson & Johnson						
Total	[REDACTED]					

<sup>149</sup> MNK-T1\_0001315847: note that the [REDACTED] listed in this document is at [REDACTED] but has the same buyer DEA number as [REDACTED]

**Figure 25 Dosage Units by Labeler Over Time: [REDACTED]**  
**(ARCOS; 2006 - 2014)**



134. Oxycodone 5mg pills labeled by Mallinckrodt made up most chargeback sales involving this [REDACTED]. A variety of opioids were found in [REDACTED] chargebacks, including formulations of oxycodone, morphine, hydrocodone, and hydromorphone that were labeled by a mixture of Mallinckrodt, Actavis, Qualitest, and Par. [REDACTED] market shares should not be compared between ARCOS and the chargeback data because labeler defendants produced differing time frames of data via chargeback data. Below is a table that breaks down top opioid drugs and dosages by chargebacks, dosage units, and MMEs in opioid chargebacks involving [REDACTED]. Also included is a table and graph that display this information per labeler, both in total and over time.

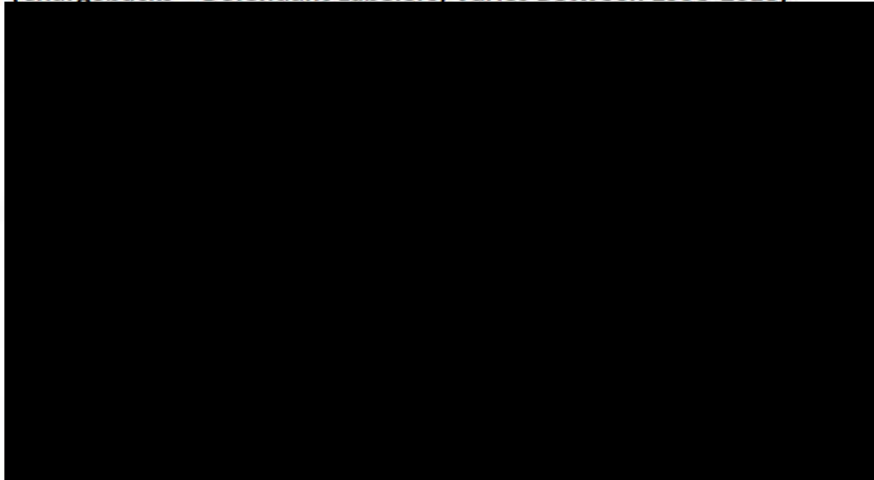
**Table 49 Transactions by Labeler and Drug and Dosage: [REDACTED]**  
**(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**

Labeler	Drug and Dosage	Pharmacy Total Chargebacks	% Pharmacy Total Chargebacks	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Mallinckrodt	Oxycodone 5mg	[REDACTED]					
Actavis	Oxycodone 10mg						
Actavis	Oxycodone 7mg						
Other Labelers	Other						
Total							

**Table 50 Transactions by Labeler:** [REDACTED]  
**(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**

Labeler Name	Pharmacy Total Chargebacks	% Pharmacy Total Chargebacks	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Actavis	[REDACTED]					
Mallinckrodt						
Par						
Qualitest						
Teva						
Total						

**Figure 26 Dosage Units Per Labeler Over Time:** [REDACTED]  
**(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**



Legend:  
 [REDACTED]  
 [REDACTED]  
 [REDACTED]  
 [REDACTED]  
 [REDACTED]  
 [REDACTED]

135. This [REDACTED] was identified by eight of the ten compliance metrics applied to buyers included in the chargeback data. Below is a table that displays the percentage of total months of chargebacks by [REDACTED] were flagged by application of compliance metrics. Also included in the table below is a column that indicates the percentage of months that the pharmacy tripped at least one compliance metric.

**Table 51 Months Flagged by Labeler:** [REDACTED]  
**(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**

*Percentage of months calculated off a labeler's own chargeback data.*

Labeler	Double National	Triple National	McKesson: 8,000	Masters: Common Sense	Qualitest: 30,000	Mallinckrodt: Rolling Average (2x)	Mallinckrodt: Rolling Average (3x)	Actavis: 125% Order	Teva: 3 Standard Deviations	Multiple Distributors	Any Flag
Actavis	[REDACTED]										
Mallinckrodt											
Par											
Qualitest											
Teva											

## 4. Flagged Pharmacy 3: [REDACTED]

136. Located at [REDACTED] in East Cleveland, this location of [REDACTED] was another pharmacy found in the chargeback data that could have been identified through labelers' SOM program. The following section describes how [REDACTED] was flagged and provides a profile of the pharmacy's transaction patterns with the labeler defendants. Totals were calculated by ARCOS and then by chargeback data to provide as complete a picture as possible of pharmacy purchasing patterns. The section ends with descriptions of the results of applying the compliance metrics to [REDACTED]

137. Teva labeled all but one opioid drug and dosage combinations that [REDACTED] purchased in amounts greater than 5% of their total transactions. Low dose hydrocodone and oxycodone labeled by Teva made up more than half of all shipments to this [REDACTED]. Purchases of Teva opioid products increased substantially from 2006 to 2007 but then remained relatively consistent, according to the annual volume of dosage units they purchased. Mallinckrodt was the only defendant labeler to identify the pharmacy as suspicious, placing them on a 2016 "cut off pharmacy" list.<sup>150</sup> Below are tables that display the drug, dosage, and labeler combinations that [REDACTED] purchased reflecting more than 5% of transactions, dosage units, and MMEs. Also included is a table and graph that display this information per labeler, both in total and over time.

**Table 52 Transactions by Labeler and Drug and Dosage:** [REDACTED]  
(ARCOS; 2006 - 2014)

Table sorted by percent of dosage units.

Labeler	Drug and Dosage	Pharmacy Total Transactions	% Pharmacy Total Transactions	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Teva	Hydrocodone 5mg	821	12.9	359,700	14.6	1,141,521	3.5
Teva	Oxycodone 10mg	404	6.3	124,100	5.0	1,668,835	5.1
Teva	Oxycodone 5mg	381	6.0	845,300	34.3	5,683,586	17.3
Mallinckrodt	Oxycodone 5mg	252	3.9	191,800	7.8	1,289,615	3.9
Purdue	Oxycodone 80mg	203	3.2	71,800	2.9	7,724,244	23.5
Purdue	Oxycodone 40mg	202	3.12	49,200	2.0	2,646,468	8.1
Teva	Codeine 30mg	126	2.0	127,400	5.2	422,350	1.3
[REDACTED]							
<b>Total</b>		<b>6,390</b>		<b>2,462,072</b>		<b>32,869,950</b>	

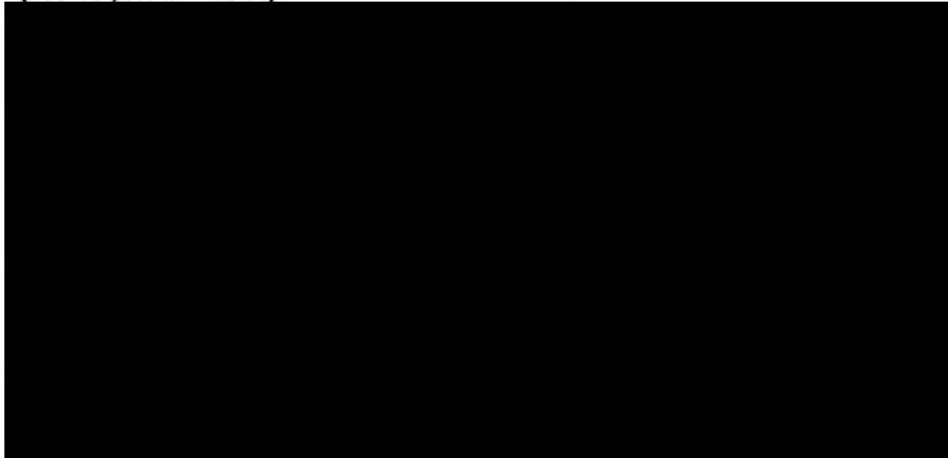
**Table 53 Transactions by Labeler:** [REDACTED]  
(ARCOS – Defendant Labelers; 2006-2014)

Labeler	Pharmacy Total Transactions	% Pharmacy Total Transactions	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Teva	3,354	60.3	1,747,155	73.5	14,035,063	46.3
Purdue	722	13.0	163,900	6.9	11,840,461	39.0
Mallinckrodt	693	12.5	282,020	11.9	2,136,785	7.0
[REDACTED]						
Johnson & Johnson	171	3.1	6,270	0.3	756,516	2.5
<b>Total</b>	<b>5,563</b>		<b>2,376,835</b>		<b>30,349,000</b>	

<sup>150</sup> MNK-T1\_0001315847



Figure 27 Dosage Units by Labeler Over Time: [REDACTED]  
(ARCOS; 2006 - 2014)



Legend: [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

138. All of [REDACTED] chargebacks were for low dose oxycodone or hydrocodone. More than four million MMEs were found in chargebacks involving oxycodone 5mg doses labeled by Actavis and Teva. [REDACTED] had hardly any chargebacks prior to 2011, when chargebacks involving Actavis opioids increased significantly only to decline two years later. Chargeback data was relatively consistent with ARCOS shipment data, although market shares should not be compared between ARCOS and the chargeback data because labeler defendants produced differing time frames of data via chargeback data. Below is a table that breaks down top opioid drugs and dosages from chargebacks involving [REDACTED]. Also included is a table and chart that display labeler market share in total and over time.

Table 54 Transactions by Labeler and Drug and Dosage: [REDACTED]  
(Chargebacks – Defendant Labelers; Varies Between 1998-2018)

Table sorted by percent of chargebacks.

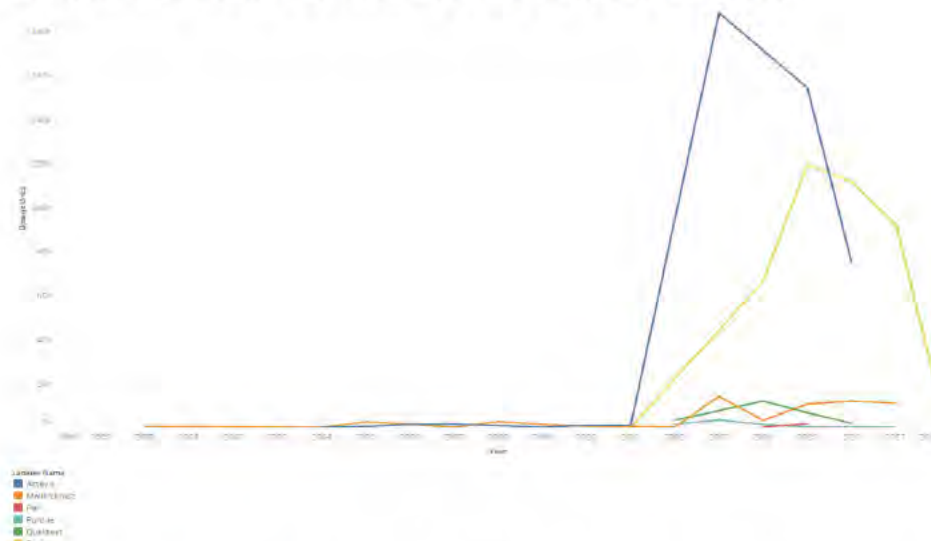
Labeler Name	Drug and Dosage	Pharmacy Total Chargebacks	% Pharmacy Total Chargebacks	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Actavis	Oxycodone 5mg	251	11.0	350,000	32	2,625,000	26.2
Actavis	Oxycodone 10mg	226	9.9	71,100	6.5	1,066,500	10.6
Teva Pharmaceuticals	Oxycodone 5mg	207	9.1	260,500	23.8	1,953,750	19.5
Mallinckrodt Inc	Oxycodone 5mg	170	7.5	49,800	4.6	373,500	3.7
Actavis	Oxycodone 7mg	155	6.8	29,500	2.7	331,875	3.3
Teva Pharmaceuticals	Oxycodone 10mg	152	6.7	40,200	3.7	603,000	6.0
Actavis	Hydrocodone 5mg	149	6.6	91,800	8.34	459,000	4.6
Other Labelers	Other	835	36.7	197,830	18.1	2,021,729	20.2
<b>Total</b>		<b>2,145</b>		<b>1,090,730</b>		<b>9,434,354</b>	



**Table 55 Transactions by Labeler:** [REDACTED]  
**(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**

Labeler Name	Pharmacy Total Chargebacks	% Pharmacy Total Chargebacks	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Actavis	1,095	48.1	596,695	54.5	5,132,827	51.2
Mallinckrodt	264	11.6	61,800	5.6	625,650	6.2
Par	19	0.8	2,060	0.2	48,450	0.5
Purdue	64	2.8	7,220	0.7	630,600	6.3
Qualitest	84	3.7	24,360	2.2	178,950	1.8
Teva	750	33.0	402,995	36.8	3,405,061	34.0
<b>Total</b>	<b>2,276</b>		<b>1,095,130</b>		<b>10,021,538</b>	

**Figure 28 Dosage Units Per Labeler Over Time:** [REDACTED]  
**(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**



139. [REDACTED] was identified by nine of the ten compliance metrics applied to chargeback. Below is a table that displays the percentage of total months of chargebacks by [REDACTED] that were flagged by application of compliance metrics. Also included in the table below is a column that indicates the percentage of months that the pharmacy tripped at least one compliance metric.

**Table 56 Months Flagged by Labeler:** [REDACTED]  
**(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**

*Percentage of months calculated off a labeler's own chargeback data.*

Labeler	Double National	Triple National	McKesson: 8,000	Masters: Common Sense	Qualitest: 30,000	Mallinckrodt: Rolling Average (2x)	Mallinckrodt: Rolling Average (3x)	Actavis: 125% Order	Teva: 3 Standard Deviations	Multiple Distributors	Any Flag
Actavis	60.7	29.5	44.3	32.8	0.0	19.7	8.2	62.3	11.5	0.0	73.8
Mallinckrodt	9.1	7.8	0.0	24.7	0.0	11.7	7.8	45.5	1.3	1.3	59.7
Par	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Purdue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	18.8	0.0	3.1	21.9
Qualitest	18.2	6.1	0.0	18.2	0.0	3.0	3.0	9.1	6.1	0.0	27.3
Teva	46.2	11.5	26.9	38.5	0.0	13.5	1.9	75.0	28.9	0.0	86.5

## 5. Flagged Pharmacy 4: [REDACTED]

140. Located at [REDACTED] in Cuyahoga Falls, [REDACTED] was another pharmacy that could have been identified by labeler's SOM programs. The following section describes how [REDACTED] was flagged by the compliance metrics and provides a profile of the pharmacy's transaction patterns with the labeler defendants. Totals were calculated by ARCOS and then by chargeback data to provide as complete a picture as possible of pharmacy purchasing patterns. The section ends with the results of applying the compliance metrics to [REDACTED]

141. A pharmacy co-located with hospitals in Summit and Cuyahoga counties, [REDACTED] purchased opioids in far greater volume relative to other pharmacies from 2006 through 2009. According to ARCOS data, [REDACTED] purchased enough Mallinckrodt-labeled opioids alone to supply Summit County with more than three million dosage units in just eight years. Oxycodone and hydrocodone accounted for the pharmacy's most purchased opioids, both labeled by Mallinckrodt. Most of the pharmacy's purchases occurred prior to 2010, after which dosage units of all defendant-labeled opioids began to decline. Mallinckrodt was the only defendant labeler to identify the pharmacy as suspicious, placing them on a 2016 "cut off pharmacy" list.<sup>151</sup> Below are tables that display the drug, dosage, and labeler combinations that [REDACTED] purchased reflecting more than 5% of transactions, dosage units, and MMEs. Also included is a table and graph that display this information per labeler, both in total and over time.

**Table 57 Transactions by Labeler and Drug and Dosage:** [REDACTED]  
(ARCOS; 2006 - 2014)

*Table sorted by percent of dosage units.*

Labeler	Drug and Dosage	Pharmacy Total Transactions	% Pharmacy Total Transactions	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Mallinckrodt	Oxycodone 5mg	1,313	6.6	2,612,000	23.4	17,562,435	5.9
Mallinckrodt	Hydrocodone 5mg	1,224	6.2	656,200	5.9	1,986,317	0.7
Mylan	Fentanyl 0.1mg	254	1.3	17,645	0.2	17,997,900	6.0
Other Labelers	Other	15,213	76.8	6,686,146	59.8	244,559,348	81.6
<b>Total</b>		<b>18,788</b>		<b>11,174,591</b>		<b>298,277,961</b>	

**Table 58 Transactions by Labeler:** [REDACTED]  
(ARCOS; 2006-2014)

Labeler	Pharmacy Total Transactions	% Pharmacy Total Transactions	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Mallinckrodt	6,043	42.6	5,648,320	57.0	76,636,536	34.9
Teva Pharmaceutical	2,644	18.6	1,224,569	12.4	55,610,900	25.3
Johnson & Johnson Pharmaceutical	832	5.9	47,000	0.5	26,139,200	11.9
Purdue	641	4.5	208,920	2.1	11,490,112	5.2
<b>Total</b>	<b>14,198</b>		<b>9,909,889</b>		<b>219,481,158</b>	

<sup>151</sup> MNK-T1\_0001315847

**Figure 29 Dosage Units by Labeler Over Time:** [REDACTED]  
**(ARCOS- Defendant Labelers; 2006 - 2014)**



Legend: [REDACTED]  
 [REDACTED]  
 [REDACTED]  
 [REDACTED]  
 [REDACTED]  
 [REDACTED]  
 [REDACTED]

142. As shown in ARCOS data, chargebacks showed the same top two opioid drug and dosage combinations to be the most frequently purchased by [REDACTED]: oxycodone 5mg and hydrocodone 5mg. As with other pharmacy examples, market shares should not be compared between ARCOS and chargeback data due to the discrepancies in the time periods.

143. Although [REDACTED] is a retail pharmacy located in a hospital, the volume of chargebacks and number of flagged transactions remain disproportionate. For reference, during the same time period, the retail pharmacy at the main campus of Cleveland Clinic submitted fewer chargeback requests for all labelers combined than [REDACTED] did for just one labeler - Qualitest. Though both pharmacies submitted the most chargebacks to Mallinckrodt [REDACTED] [REDACTED] chargebacks to Mallinckrodt in terms of MMEs were roughly 40 times greater than Cleveland Clinic's. A breakdown of Cleveland Clinic's chargebacks by labeler is included below for comparison. The tables that follow break down top opioid drug and dosages from chargebacks involving [REDACTED]. Also included is a table and chart that display labeler market share both in total and over time.

**Table 59 Comparison Transactions by Labeler:** [REDACTED]  
**(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**

Labeler Name	Pharmacy Total Chargebacks	% Pharmacy Total Chargebacks	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Actavis	69	5.4	19,315	3.6	259,325	4.9
Mallinckrodt	895	70.1	470,400	86.9	3,474,600	65.2
Purdue	304	23.8	50,600	9.3	1,589,792	29.8
Qualitest	9	0.7	1,190	0.2	5,625	0.1
<b>Total</b>	<b>1277</b>		<b>541,505</b>		<b>5,329,342</b>	



**Table 60 Transactions by Labeler and Drug and Dosage:**  
**(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**

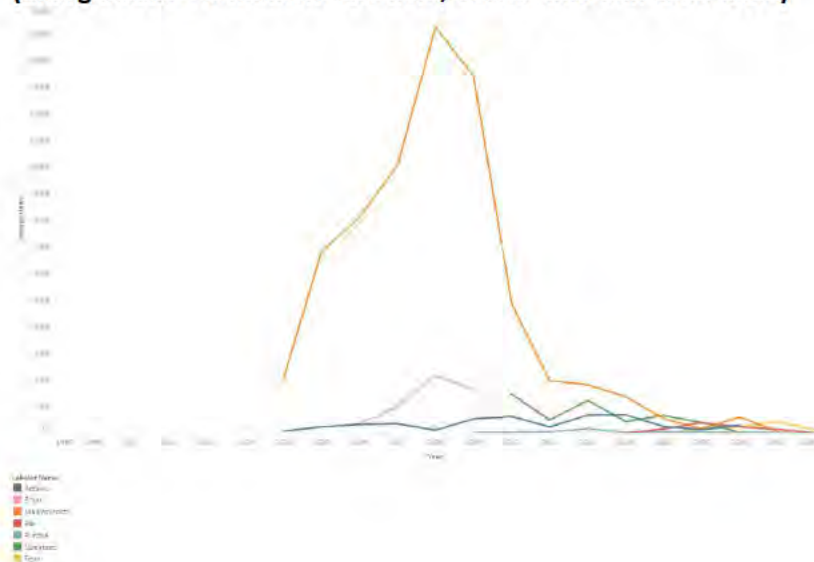
Table sorted by percent of chargebacks.

Labeler	Drug and Dosage	Pharmacy Total Chargebacks	% Pharmacy Total Chargebacks	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Mallinckrodt	Oxycodone 5mg	1,505	12.3	3,196,800	38.0	23,976,000	17.8
Mallinckrodt	Hydrocodone 5mg	1,495	12.3	816,800	9.7	4,084,000	3.0
Mallinckrodt	Hydromorphone 4mg	406	3.3	452,400	5.4	7,238,400	5.4
Mallinckrodt	Morphine 30mg	476	3.9	426,700	5.1	12,801,000	9.5
Mallinckrodt	Morphine 60mg	229	1.9	300,800	3.6	18,048,000	13.4
Mallinckrodt	Hydrocodone 7mg	644	5.3	223,576	2.7	1,676,820	1.3
Mallinckrodt	Morphine 100mg	257	2.1	160,400	1.9	16,040,000	11.9
Mallinckrodt	Hydrocodone 10mg	628	5.2	126,100	1.5	1,261,000	0.9
Other Labelers	Other	6,465	53.0	2,701,740	32.1	49,332,480	36.6
<b>Total</b>		<b>12,105</b>		<b>8,405,316</b>		<b>134,457,700</b>	

**Table 61 Transactions by Labeler:**  
**(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**

Labeler Name	Pharmacy Total Chargebacks	% Pharmacy Total Chargebacks	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Actavis	2,080	17.1	456,445	5.4	6,542,376	4.9
Endo	390	3.2	518,000	6.2	8,006,875	6.0
Mallinckrodt	7,158	58.7	6,716,661	79.9	109,306,644	81.2
Par	278	2.3	95,030	1.1	688,171	0.5
Purdue	502	4.1	49,080	0.6	1,586,032	1.2
Qualitest	1,292	10.6	474,200	5.6	7,721,451	5.7
Teva	498	4.1	95,900	1.1	801,927	0.6
<b>Total</b>	<b>12,198</b>		<b>8,405,316</b>		<b>134,653,476</b>	

**Figure 30 Dosage Units by Labeler Over Time:**  
**(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**



144. [REDACTED] was identified as suspicious by Cardinal Health as well as by the other compliance metrics applied in this report.<sup>152</sup> Cardinal stopped shipments of controlled substances to New Choice in December 2007 but began them again in early 2008 after lowering their threshold for [REDACTED]. [REDACTED] also triggered nine of the ten compliance metrics. Below is a table that displays the percentage of total months of chargebacks by [REDACTED] were flagged by application of compliance metrics.

**Table 62 Months Flagged by Labeler: [REDACTED]  
(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**

*Percentage of months calculated off a labeler's own chargeback data.*

Labeler	Double National	Triple National	McKesson: 8,000	Masters: Common Sense	Qualitest: 30,000	Mallinckrodt: Rolling Average (2x)	Mallinckrodt: Rolling Average (3x)	Actavis: 125% Order	Teva: 3 Standard Deviations	Multiple Distributor	Any Flag
Actavis	72.9	55.7	5.7	41.4	0.0	16.4	7.9	58.6	20.0	0.0	87.1
Endo	83.7	74.4	51.2	37.2	0.0	25.6	14.0	60.5	25.6	0.0	88.4
Mallinckrodt	84.2	69.5	62.8	56.7	0.0	17.1	7.9	81.7	22.0	13.4	93.9
Par	19.0	12.1	1.7	15.5	0.0	17.2	6.9	12.1	8.6	0.0	29.3
Purdue	5.7	3.8	0.0	25.5	0.0	9.4	5.7	17.0	8.5	0.0	34.9
Qualitest	48.1	19.5	9.1	31.2	0.0	19.5	6.5	62.3	18.2	0.0	77.9
Teva	32.1	22.6	1.9	32.1	0.0	26.4	15.1	34.0	5.7	1.9	56.6

#### 6. Flagged Pharmacy 5: [REDACTED]

145. Located at [REDACTED] in Cleveland, OH – just across the parking lot from the [REDACTED] at [REDACTED] – [REDACTED] is another entity that could have been known and flagged by labelers. The following section describes how [REDACTED] was flagged and provides a profile of the pharmacy's transaction patterns with the labeler defendants. Totals were calculated by ARCOS and then by chargeback data to provide as complete a picture as possible of pharmacy purchasing patterns. The section ends with the results of applying the compliance metrics to [REDACTED].

146. According to ARCOS data, two of the four opioid drug and dosage types most involved in [REDACTED] transactions were 40mg and 80mg oxycodone labeled by Purdue. The only drug and dosage that accounted for a higher percentage of transactions was Mallinckrodt-labeled oxycodone 5mg. Overall, Purdue and Mallinckrodt labeled a similar proportion of opioids purchased by [REDACTED]. Both labelers were responsible for roughly 36% of transactions. Mallinckrodt labeled more dosage units, while Purdue was responsible for the greater percentage of MMEs – likely due to their products being high dose. The pharmacy's purchases increased rapidly with every year from 2008 to 2011 – particularly of Mallinckrodt-labeled opioids – and then either declined or leveled off for the remaining years of the period. Mallinckrodt was the only defendant labeler to identify the pharmacy as suspicious, placing them on a 2016 "cut off pharmacy" list.<sup>153</sup> Below are tables that display the drug, dosage, and labeler combinations that [REDACTED] purchased reflecting more than 5% of transactions, dosage units, and MMEs. Also included is a table and graph that display this information per labeler, both in total and over time.

<sup>152</sup> AH\_MDL\_PRIORPROD\_DEA07\_00006195

<sup>153</sup> MNK-T1\_0001315847



**Table 63 Transactions by Labeler and Drug and Dosage**  
**(ARCOS; 2006 - 2014)**

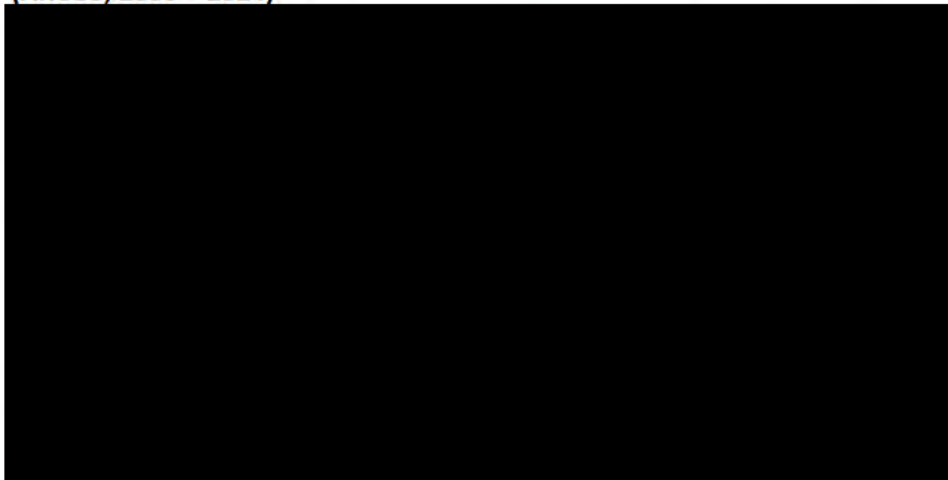
*Table sorted by percent of dosage units.*

Labeler	Drug and Dosage	Pharmacy Total Transactions	% Pharmacy Total Transactions	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Mallinckrodt	Oxycodone 5mg	968	11.0	1,787,400	45.6	12,018,031	13.9
Purdue	Oxycodone 80mg	793	9.0	278,860	7.1	29,999,759	34.7
Mallinckrodt	Oxycodone 10mg	393	4.5	256,500	6.5	3,449,284	4.0
Purdue	Oxycodone 40mg	509	5.8	121,140	3.1	6,516,121	7.5
<b>Total</b>		<b>8,463</b>		<b>3,921,195</b>		<b>85,877,537</b>	

**Table 64 Transactions by Labeler:**  
**(ARCOS; 2006-2014)**

Labeler	Pharmacy Total Transactions	% Pharmacy Total Transactions	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Purdue	2,720	37.5	621,220	17.0	43,291,894	54.7
Mallinckrodt	2,608	36.0	2,419,430	66.2	23,024,948	29.1
Endo	1,080	14.9	325,800	8.9	7,904,628	10.0
Teva	704	9.7	283,275	7.8	2,999,472	3.8
Johnson & Johnson	134	1.9	2,640	0.1	1,990,400	2.5
<b>Total</b>	<b>7,246</b>		<b>3,652,365</b>		<b>79,211,342</b>	

**Figure 31 Dosage Units by Labeler Over Time:**  
**(ARCOS; 2006 – 2014)**



Labeler Name Grouped by Pillar:  
 ■ Endo  
 ■ Johnson & Johnson  
 ■ Mallinckrodt  
 ■ Purdue  
 ■ Teva

147. Chargebacks for [REDACTED] reflected similar overall trends as found in ARCOS. Oxycodone 5mg pills labeled by Mallinckrodt made up the greatest portion of [REDACTED] opioids chargebacks, by any metric. Purdue-labeled oxycodone 80mg and 40mg combined made up more than 19% of the pharmacy's chargeback total – compared to the 14% for which Mallinckrodt

oxycodone 5mg accounted. [REDACTED] was not involved in any labeler defendant-related chargebacks prior to 2008, when chargebacks increased for purchases of Mallinckrodt- and Purdue-labeled opioids until peaking in 2011. Increases in chargebacks for other labeler defendants were less dramatic but reached the same overall peak. Market shares should not be compared between ARCOS and the chargeback data because of discrepancies in time periods, as described above. Below is a table displaying top opioid drug and dosages from chargebacks involving [REDACTED]. Also included is a table and chart that display labeler market share.

**Table 65 Transactions by Labeler and Drug and Dosage: [REDACTED]**  
**(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**

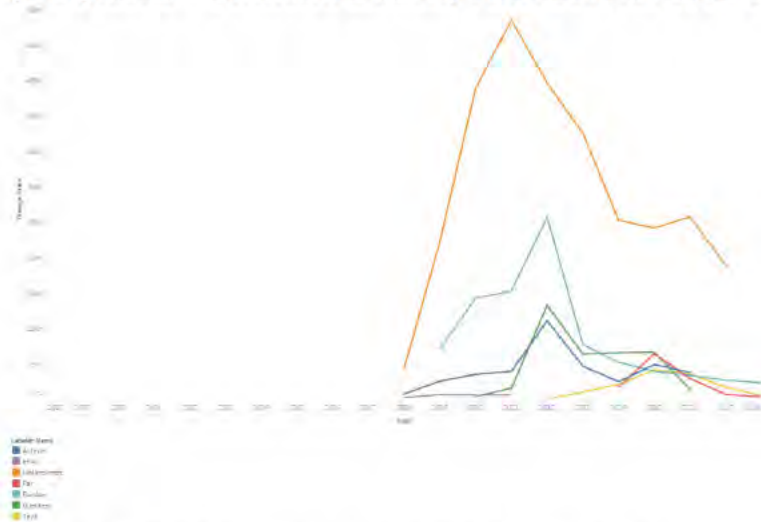
*Table sorted by percent of chargebacks.*

Labeler Name	Drug and Dosage	Pharmacy Total Chargebacks	% Pharmacy Total Chargebacks	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Mallinckrodt	Oxycodone 5mg	1,609	14.6	2,386,100	48.8	17,895,750	16.4
Purdue	Oxycodone 80mg	1,244	11.3	375,160	7.7	45,019,200	41.2
Mallinckrodt	Oxycodone 10mg	491	4.5	289,500	5.9	4,342,500	4.0
Purdue	Oxycodone 40mg	922	8.4	177,340	3.6	10,640,400	9.7
Purdue	Oxycodone 20mg	632	5.8	99,600	2.0	2,988,000	2.7
Purdue	Oxycodone 60mg	473	4.3	61,800	1.3	5,562,000	5.1
Other Labelers	Other	5,560	50.8	1,498,120	30.7	22,772,744	20.8
<b>Total</b>		<b>10,931</b>		<b>4,887,620</b>		<b>109,220,594</b>	

**Table 66 Transactions by Labeler: [REDACTED]**  
**(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**

Labeler Name	Pharmacy Total Chargebacks	% Pharmacy Total Chargebacks	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Actavis	1,136	10.3	377,500	7.7	5,302,246	4.9
Endo	69	0.6	21,200	0.4	520,475	0.5
Mallinckrodt	3,599	32.8	3,006,330	61.5	27,114,344	24.8
Par	296	2.7	121,000	2.5	862,400	0.8
Purdue	4,366	39.7	877,860	18.0	67,974,050	62.2
Qualitest	956	8.7	363,200	7.4	4,438,550	4.1
Teva	567	5.2	120,530	2.5	3,113,383	2.9
<b>Total</b>	<b>10,989</b>		<b>4,887,620</b>		<b>109,325,448</b>	

**Figure 32 Dosage Units by Labeler Over Time: [REDACTED]**  
**(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**



148. [REDACTED] was identified by nine of the ten compliance metrics. Below is a table that displays the percentage of total months of chargebacks by [REDACTED] that were flagged by the methodology. Also included in the table below is a column that indicates the percentage of months that the pharmacy tripped at least one compliance metric.

**Table 67 Months Triggered Per Labeler: [REDACTED]**  
**(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**

*Percentage of months calculated off a labeler's own chargeback data.*

Labeler	Double National	Triple National	McKesson: 8,000	Masters: Common Sense	Qualitest: 30,000	Mallinckrodt: Rolling Average (2x)	Mallinckrodt: Rolling Average (3x)	Actavis: 125% Order	Teva: 3 Standard Deviations	Multiple Distributor	Any Flag
Actavis	30.6	29.6	6.1	44.9	0.0	32.7	13.3	68.4	16.3	0.0	77.6
Endo	2.7	2.7	0.0	24.3	0.0	8.1	2.7	35.1	10.8	0.0	40.5
Mallinckrodt	97.4	91.3	93.9	57.4	0.0	25.2	8.7	94.8	18.3	32.2	97.4
Par	46.0	24.3	0.0	29.7	0.0	2.7	2.7	21.6	2.7	0.0	59.5
Purdue	99.1	99.1	28.7	21.7	0.0	7.0	1.7	84.4	7.8	14.8	100.0
Qualitest	62.0	40.9	7.0	39.4	0.0	23.9	15.5	67.6	23.9	0.0	93.0
Teva	52.9	47.1	0.0	29.4	0.0	17.7	5.9	39.2	13.7	0.0	58.8

## 7. Flagged Pharmacy 6: [REDACTED]

149. Located at [REDACTED] in Akron, [REDACTED] is another entity that could have been known and flagged by labelers. The following section describes how [REDACTED] was flagged by compliance metrics and provides a profile of the pharmacy's transaction patterns with the labeler defendants. Totals were calculated by ARCOS and then by chargeback data to provide as complete a picture as possible of pharmacy purchasing patterns. The section ends with the results of applying the compliance metrics to [REDACTED]

150. According to ARCOS data, Mallinckrodt products made up more than one-third of all dosage units purchased by the pharmacy. However, [REDACTED] purchases of Mallinckrodt-labeled opioids declined consistently from their peak in 2009 until 2013. Just as purchases of Mallinckrodt products declined [REDACTED] purchases of Endo products sharply increased. Other labelers labeled



comparatively smaller percentages of opioids bought by the [REDACTED] on [REDACTED].  
Mallinckrodt was the only defendant labeler to identify the pharmacy as suspicious, placing them on a 2016 "cut off pharmacy" list.<sup>154</sup>

151. [REDACTED] was connected to Flagged Prescriber #5, Adolph Harper. The pharmacy was located roughly two miles from Harper's practice on [REDACTED]. This [REDACTED] requested that McKesson increase its threshold on oxycodone by on two occasions because of "increased activity from a local pain mgmt. doctor," Adolph Harper (though one request was denied).<sup>155</sup> Below are tables that display the drug, dosage, and labeler combinations that [REDACTED] purchased reflecting more than 5% of transactions, dosage units, and MMEs. Also included is a table and graph that display this information per labeler, both in total and over time.

**Table 68 Transactions by Labeler and Drug and Dosage:** [REDACTED]  
(ARCOS - Defendant Labelers; 2006 - 2014)

*Table sorted by percent of dosage units.*

Labeler	Drug and Dosage	Pharmacy Total Transactions	% Pharmacy Total Transactions	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Mallinckrodt	Hydrocodone 5mg	282	4.6	502,200	16.2	1,520,159	3.6
Mallinckrodt	Oxycodone 5mg	270	4.4	350,700	11.3	2,358,019	5.7
[REDACTED]							
Mallinckrodt	Hydrocodone 7.5mg	380	6.2	235,800	7.6	1,071,939	2.6
Purdue	Oxycodone 80mg	147	2.4	45,900	1.5	4,937,922	11.8
[REDACTED]							
<b>Total</b>		<b>5,943</b>		<b>3,106,770</b>		<b>41,675,072</b>	

**Table 69 Transactions by Labeler:** [REDACTED]  
(ARCOS – Defendant Labelers; 2006-2014)

Labeler	Pharmacy Total Transactions	% Pharmacy Total Transactions	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Mallinckrodt	1,834	39.7	1,439,025	53.1	10,374,852	30.6
[REDACTED]						
Teva	720	15.6	201,115	7.4	4,994,907	14.7
Purdue	470	10.2	120,800	4.5	8,285,430	24.4
Johnson & Johnson	138	3.0	2,855	0.1	1,355,250	4.0
<b>Total</b>	<b>4,624</b>		<b>2,711,925</b>		<b>33,940,445</b>	

<sup>154</sup> MNK-T1\_0001315847

<sup>155</sup> MCKMDL00632908 & MCKMDL00626683, Deposition of Sophia Lai Novack

Figure 33 Dosage Units by Labeler Over Time: [REDACTED]  
(ARCOS; 2006 - 2014)



152. Mallinckrodt- and Qualitest-labeled oxycodone 5mg accounted for the greatest volume of dosage units included in chargebacks. Qualitest chargebacks increased dramatically in 2011 – at which point Mallinckrodt chargebacks had begun decreasing significantly. Below is a table displaying top opioid drug and dosages from chargebacks involving [REDACTED]. Also included is a table and chart that display labeler market share. Note that conclusions could not be drawn between comparisons of market shares in ARCOS and the chargeback data because of discrepancies in the produced time periods, as described above.

Table 70 Transactions by Labeler and Drug and Dosage: [REDACTED]  
(Chargebacks – Defendant Labelers; Varies Between 1998-2018)

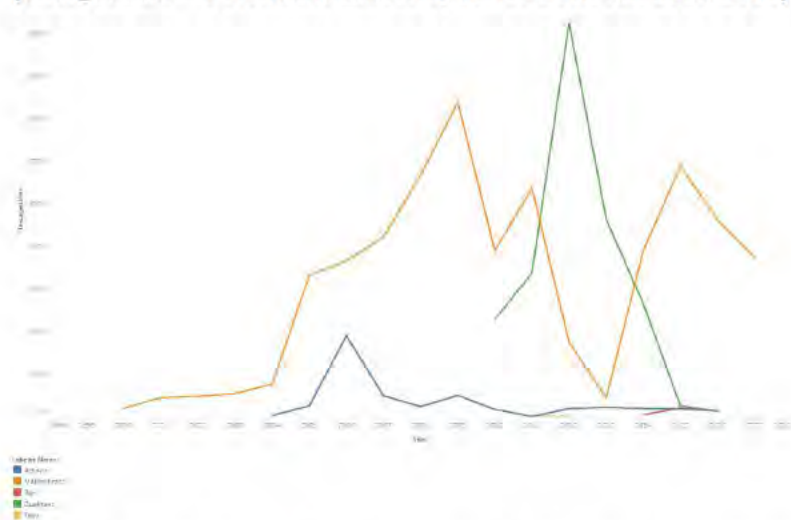
Labeler Name	Drug and Dosage	Pharmacy Total Chargebacks	% Pharmacy Total Chargebacks	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Mallinckrodt	Oxycodone 5mg	416	14.3	433,900	25.9	3,254,250	15.9
Qualitest	Oxycodone 5mg	323	11.1	365,300	21.8	2,739,750	13.3
Mallinckrodt	Hydrocodone 5mg	263	9.1	229,300	13.7	1,146,500	5.6
Mallinckrodt	Oxycodone 10mg	204	7.0	159,800	9.5	2,397,000	11.7
Mallinckrodt	Hydrocodone 7mg	201	6.9	92,664	5.5	694,980	3.4
Mallinckrodt	Hydrocodone 10mg	200	6.9	74,600	4.5	746,000	3.6
Mallinckrodt	Oxycodone 30mg	70	2.4	33,400	2.0	1,503,000	7.3
Actavis	Oxycodone 40mg	42	1.5	19,500	1.2	1,170,000	5.7
Actavis	Oxycodone 80mg	27	0.9	9,700	0.6	1,164,000	5.7
Other Labelers	Other	1,117	38.5	259,030	15.4	5,690,476	28
<b>Total</b>		<b>2,863</b>		<b>1,677,194</b>		<b>20,505,956</b>	



**Table 71 Transactions by Labeler:** [REDACTED]  
**(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**

Labeler Name	Pharmacy Total Chargebacks	%Pharmacy Total Chargebacks	Pharmacy Total Dosage Units	% Pharmacy Total Dosage Units	Pharmacy Total MMEs	% Pharmacy Total MMEs
Actavis	314	10.8	90,045	5.4	3,599,280	17.5
Mallinckrodt	1,878	64.7	1,127,169	67.2	12,316,443	60.0
Par	68	2.3	7,590	0.5	133,122	0.7
Qualitest	638	22.0	451,890	26.9	4,484,477	21.8
Teva	5	0.2	500	0.0	3,250	0.0
<b>Total</b>	<b>2,903</b>		<b>1,677,194</b>		<b>20,536,572</b>	

**Figure 34 Dosage Units by Labeler Over Time:** [REDACTED]  
**(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**



153. Below is a table that displays the number of months for which the pharmacy triggered each compliance metric in the chargeback data by methodology. Also included in the table below is a column that indicates how many months of data for chargeback requests per labeler the produced data included to provide context for the quantity of chargeback data received from each labeler defendant as compared to what was flagged by the respective metrics. Figures are conservative, as the pharmacy may have been flagged more than once per month based on purchasing patterns of individual drugs.

**Table 72 Months Flagged by Labeler:** [REDACTED]  
**(Chargebacks – Defendant Labelers; Varies Between 1998-2018)**

*Percentage of months calculated off a labeler's own chargeback data.*

Labeler	Double National	Triple National	McKesson: 8,000	Masters: Common Sense	Qualitest: 30,000	Mallinckrodt: Rolling Average (2x)	Mallinckrodt: Rolling Average (3x)	Actavis: 125% Order	Teva: 3 Standard Deviations	Multiple Distributor	Any Flag
Actavis	16.2	17.2	0.0	22.2	0.0	17.2	9.1	27.3	7.1	0.0	47.5
Mallinckrodt	46.3	28.4	22.4	45.8	0.0	33.8	16.4	73.6	22.9	0.5	82.6
Par	16.7	4.2	0.0	25.0	0.0	4.2	0.0	29.2	0.0	0.0	41.7
Qualitest	63.4	56.3	29.6	45.1	0.0	22.5	14.1	60.6	9.9	0.0	90.1
Teva	0.0	0.0	0.0	9.4	0.0	0.0	0.0	9.4	6.3	0.0	15.6

## M. Downstream Customers of Suspicious Orders

154. Mallinckrodt produced over 70,000 records containing what they deemed peculiar purchases made by distributors and sent to distribution centers around the country. Over 58,500 of these records were for opioids (not including medically-assisted treatment drugs).<sup>156</sup> The documents contained peculiar order reports specifically prepared by Mallinckrodt for this litigation to demonstrate the scope of their peculiar order monitoring.

155. In addition to the produced data, internal Mallinckrodt communications show employees actively monitoring nationwide chargeback data as received from their direct customers to glean information about potential diversion happening at the downstream customer level. While many different business activities are downstream customers, I limited this portion of the analysis only to pharmacies. Beginning no later than 2010, Mallinckrodt was monitoring customer purchasing habits for the ratio of controlled to non-controlled substances and the number of different distributors that a customer ordered from.<sup>157</sup> Two formulations of oxycodone were specifically monitored— oxycodone 15mg and 30 mg<sup>158</sup> – as well as hydrocodone/APAP.<sup>159</sup> Mallinckrodt went so far as to specifically exclude oxycodone 15mg and 30mg from sales and rebate agreements with buyers at a time when they were rewriting customer agreements that encouraged collection of chargeback data.<sup>160</sup> Mallinckrodt was also acutely aware in 2010 of the large percentage of its oxycodone products that were purchased with cash in the state of Florida, another key indicator of the potential for diversion.<sup>161</sup>

156. As neither Summit nor Cuyahoga counties were the home of any major distributor, none of the listed recipients in the peculiar transactions data were located in these counties. I was directed by counsel to determine if I could trace the purchase by buyers located in Summit or Cuyahoga counties of a particular NDC product, bought around the time Mallinckrodt deemed the order peculiar. Mallinckrodt also produced chargeback data that contained information regarding purchases by pharmacies and other end buyers.<sup>162</sup> I used this data to identify Summit and Cuyahoga buyers that purchased an opioid product from a distributor within three days (before or after) of that distributor being deemed peculiar by Mallinckrodt for a transaction involving that same opioid product.

157. McKesson Corporation and Cardinal Health distribution centers totaled roughly \$500 million and \$475 million, respectively in peculiar orders placed to Mallinckrodt. Some smaller distributors like the Smith Drug Company and H.D Smith were among the top five in number of transactions deemed peculiar. Below is a list of the ten largest sold to companies with peculiar transactions.

---

<sup>156</sup> MNK-T1\_0008592627

<sup>157</sup> MNK-T1 0002357154

<sup>158</sup> MNK-T1 0000368647, MNK-T1 0000368646, MNK-T1 0000280621

<sup>159</sup> MNK-T1\_0000561489, MNK-T1\_0000561491

<sup>160</sup> MNK-T1 0000368649

<sup>161</sup> MNK-T1\_0000391545

<sup>162</sup> MNK-T1\_0007965587 - MNK-T1\_0007965588

**Table 73 Largest Peculiar Order Recipients by Parent Company – Nationwide  
(Mallinckrodt Peculiar Orders; 2003, 2005-2017)**

Recipient (Parent Company)	# Peculiar Orders	% National Peculiar Orders	Total Sales	% National Sales
Amerisourcebergen Corporation	18,526	31.6	\$241,039,015	14.7
Smith Drug Co	3,575	6.1	\$39,443,135	2.4
Mckesson Corporation	3,517	6.0	\$503,541,353	30.8
H D Smith LLC	3,333	5.7	\$33,660,333	2.1
Cardinal Health	2,744	4.7	\$474,969,598	29.0
Omnicare Inc	1,379	2.4	\$7,566,683	0.5
North Carolina Mutual Drug Co Inc	1,363	2.3	\$25,781,803	1.6
Teva Pharmaceuticals	1,322	2.3	\$26,032,346	1.6
Dakota Drug	1,241	2.1	\$2,192,640	0.1
Professional Pharmacy Inc	1,203	2.1	\$442,244	0.0
Other Recipients	20,378	34.8	\$281,320,087	17.2
<b>Total</b>	<b>58,581</b>		<b>\$1,635,989,237</b>	

158. Of the 58,500 peculiar transactions, I identified around 2,900 that involved distributors that shipped the same opioid product purchased in the peculiar transaction to buyers in either Summit County or Cuyahoga County within 30 days. With chargeback data, Mallinckrodt was able to see where peculiar orders went. Below is table with lists of the ten largest distribution centers with peculiar transactions traced to Summit and Cuyahoga counties.

**Table 74 Largest Recipients by DEA Number of Peculiar Orders Traced to Summit and Cuyahoga  
(Mallinckrodt Peculiar Orders, Confidential ARCOS; 2003, 2005-2017)**

Reporter DEA No	Ship to Distribution Center (ARCOS Name and Location)	# Peculiar Orders	% National Peculiar Orders	Total Sales	% National Sales
RA0314562	Amerisourcebergen Drug Corp - Lockbourne, OH	1,039	36.3	\$15,934,766	23.7
RK0236403	Keysource Medical, Inc - Cincinnati, OH	673	23.5	\$31,525,378	46.9
RH0347282	H. D. Smith - Louisville, KY	338	11.8	\$2,466,304	3.7
RA0287020	Teva Pharmaceuticals - Groveport, OH	200	7.0	\$7,424,863	11.0
PP0031904	Prescription Supply Inc - Northwood, OH	164	5.7	\$456,162	0.7
RB0363630	Amerisourcebergen Drug Corp - North Amityville, NY	109	3.8	\$1,104,408	1.6
PM0031550	Miami-Luken - Springboro, OH	106	3.7	\$510,675	0.8
RV0464646	Value Drug Company - Duncansville, PA	70	2.5	\$534,679	0.8
RM0258601	Mckesson Corporation - New Castle, PA	52	1.8	\$2,265,225	3.4
RO0153609	Cardinal Health - Wheeling, WV	26	0.9	\$1,557,162	2.3
	Other Distribution Centers	83	2.9	\$3,491,797	5.2
	<b>Total</b>	<b>2,860</b>		<b>\$67,271,419</b>	

## N. Methodology

### 1. ARCOS Data

159. ARCOS data from SLCG was received on or about April 4, 2018. The data was used exactly as described in the McCann Expert Report filed on March 25, 2019, with two exceptions:<sup>163</sup>

- a. Morphine Milligram Equivalents (MMEs) was added to the table by multiplying the supplied MME conversion factor by the calculated base weight in grams by 1000 (to obtain milligrams).
- b. For the six labeler defendants, names as provided in the “Combined Labeler Name” were grouped under their parent companies as shown in the table below. Note that “Mallinckrodt” did not appear as a labeler in the ARCOS data from SLCG, only “SpecGx LLC”

**Table 75 Labeler Defendant Parent and Subsidiary Groupings**

Labeler Name Grouped	Combined Labeler Name
Endo	Endo Pharmaceuticals, Inc.
Endo	Par Pharmaceutical
INSYS	INSYS Therapeutics, Inc.
Johnson & Johnson	Janssen Pharmaceuticals, Inc.
Mallinckrodt	SpecGx LLC
Purdue	Purdue Pharma LP
Purdue	Purdue Frederick Company
Purdue	Rhodes Pharmaceuticals
Teva	Teva Pharmaceuticals USA, Inc.
Teva	Actavis Pharma, Inc.
Teva	Allergan, Inc.
Teva	Cephalon, Inc.
Teva	Watson Pharma, Inc.

### 2. IQVIA Xponent®

160. IQVIA Xponent® data consists of data from a representative sample of pharmacies, mail order services, and long term care facilities.<sup>164</sup> The dataset, owned and maintained by IQVIA – a healthcare information company - is used by industry “to measure market and product demand.”<sup>165</sup> On the company’s website, IQVIA describes the data as being used for tracking product demand over time, formulating “competitive sales strategies”, and developing a further understanding of pharmaceutical distribution.<sup>166</sup>

161. The IQVIA Xponent® data covered 1997 through 2018, except for 2007 and the first four months of 2016, which were not included in the original received dataset. Data was not estimated when missing in the case of 2007. However, the four missing months of 2016 (January through April) were estimated using data from May 2016 in order to complete the year.

162. Each row of the Xponent® data came with 118 fields describing two years of prescription metrics for a unique prescriber identifier and NDC pair. The fields described below were used in

<sup>163</sup> McCann, Craig J. *National Prescription Opiate Litigation*. MDL No. 2804. 17-MD-2804. 2019.

<sup>164</sup> [http://us.imshealth.com/marketing/fincom/appropriateuse\\_presentation.pdf](http://us.imshealth.com/marketing/fincom/appropriateuse_presentation.pdf)

<sup>165</sup> <https://www.iqvia.com/locations/united-states/commercial-operations/essential-information/prescription-information>

<sup>166</sup> *Ibid.*



the analysis:

- c. sra2\_md\_ims\_id: A unique identifier assigned to prescribers
- d. sra3\_md\_specialty column: The identification code for the prescriber's practice specialty
- e. product\_group\_number: An identification code for the drug product prescribed
- f. prescriber\_last\_name: The surname of the prescriber
- g. prescriber\_first\_name: The first name of the prescriber
- h. prescriber\_middle\_initial: The middle initial of the prescriber
- i. prescriber\_street\_address : Street Address in which the prescriber was located
- j. prescriber\_city: City in which the prescriber was located
- k. prescriber\_state: State in which the prescriber was located
- l. prescriber\_zipcode: Zip code in which the prescriber was located
- m. data\_date: The month ending the two-year period that the record covers
- n. num\_months\_of\_data: The number of months that the record covers

163. "Data Bucket" columns: A total of 96 columns, each named "data\_bucket\_X", with 'X' being a number between 1 and 96 and representing a single month of data in one of four categories: Total Rx, New Rx, Total Qty, and New Qty. Each category took up 24 different columns with the first 12 columns being the numbers for the more recent year and the latter 12 columns correlating to the earlier year. The table below contains the column names as they originally appeared, the column name used by Gryphon when summarizing the data, and descriptions of what the data in the columns represent

**Table 76 IQVIA Xponent® Data Bucket Mapping**

Summary Column	Original Column Source	Description
year_2_new_presc_sum	data_bucket_25_month - data_bucket_36_month	New monthly prescriptions for the corresponding drug in year of the data_date, in reverse order (Dec – Jan)
year_1_new_presc_sum	data_bucket_37_month - data_bucket_48_month	New monthly prescriptions for the corresponding drug in year before the data_date, in reverse order (Dec – Jan)
year_2_total_presc_sum	data_bucket_73_month - data_bucket_84_month	Total monthly prescriptions for the corresponding drug in year of the data_date, in reverse order (Dec – Jan)
year_1_total_presc_sum	data_bucket_85_month - data_bucket_96_month	Total monthly prescriptions for the corresponding drug in year before the data_date, in reverse order (Dec – Jan)
year_2_new_doses_sum	data_bucket_73_month - data_bucket_84_month	New monthly prescribed doses for the corresponding drug in year of the data_date, in reverse order (Dec – Jan)
year_1_new_doses_sum	data_bucket_85_month - data_bucket_96_month	New monthly prescribed doses for the corresponding drug in year before the data_date, in reverse order (Dec – Jan)
year_2_total_doses_sum	data_bucket_73_month - data_bucket_84_month	Total monthly prescribed doses for the corresponding drug in year of the data_date, in reverse order (Dec – Jan)
year_1_total_doses_sum	data_bucket_85_month - data_bucket_96_month	Total monthly prescribed doses for the corresponding drug in year before the data_date, in reverse order (Dec – Jan)



## a. Supplementing the Data - Drug Information

164. The IQVIA “product group code” was an internal identifier used by the company to identify the drug product prescribed. A supplemental file<sup>167</sup> contained information linking this code to a product description and manufacturer. This information was used to supplement the data with the following fields:

- o. Drug Name: the product description was used to identify the drug name for the prescribed drug product. For example, if the product description was “OXYCODONE/APAP,TAB,5MG,10 2164-10 (RX)”, the drug name was identified as “OXYCODONE”.
- p. Active Numerator Strength (Drug Strength): the product description was used to determine the “active numerator strength” of the drug product, which describes the milligrams per pill. For example, if the product description was “OXYCODONE/APAP,TAB,5MG,10 2164-10 (RX)”, the active numerator strength was identified as 5.
- q. Labeler Name: The manufacturer name provided was renamed as necessary to make it consistent with names as used in other datasets and grouped under the parent entity.

**Table 77 Labeler Parent and IQVIA Manufacturer Mapping**

Labeler Name Grouped	IQVIA Manufacturer
Abbott	Abbott Pharm Prods
Abbvie	Abbvie Inc.
Bristol-Myers Squibb	Bristol-M Sq Us Ph
Endo	Endo Generic Prod
Endo	Endo Labs
Endo	Par Pharm
Johnson & Johnson	Janssen Pharm
Mallinckrodt	Mallinckrodt
Mckesson	Mckesson Labs
Mckesson	Mckesson Pkg Serv
Mylan	Mylan
Mylan	Mylan Bertek
Mylan	Mylan Institution
Mylan	Mylan Specialty
Pfizer Inc	Pfizer
Purdue	Purdue Pharma
Teva	Allergan
Teva	Teva CNS
Teva	Teva Parenteral Med
Teva	Teva Pharmaceuticals

- r. MME Conversion Factor: The CDC published “MME conversion factors” that allow for drugs to be compared to one another by converting different drugs and dosage strengths into morphine milligram equivalents (MME). Per the CDC guidelines, there are multiple MME conversions for Fentanyl depending on the application; 100 was the most conservative option and was applied for reporting and identifying potential opioid overutilizers.<sup>168</sup>

<sup>167</sup> GPS 084 71 USC022 mkt def APR2018

<sup>168</sup> “Overview,” CMS.gov Centers for Medicare & Medicaid Services, 3 Apr. 2019, [www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/](http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/).

**Table 78 MME Conversion Factors Applied to IQVIA**

Drug Name	MME Conversion Factor
Codeine	0.15
Dihydrocodeine	0.25
Oxycodone	1.5
Hydromorphone	4
Hydrocodone	1
Levorphanol	11
Meperidine	0.10
Morphine	1
Oxymorphone	3
Tapentadol	0.40
Fentanyl	100

- s. MMEs: Morphine milligram equivalents were added based upon the below formula, based on active numerator strength, number of doses, and MME conversion factor.

$$MMEs = (active\ numerator\ strength \times doses) \times MME\ conversion\ factor$$

- b. Supplementing the Data - Prescriber Information
- t. Each prescriber in the original IQVIA data had identifying information relating to their name, place of business, and medical specialty. The following information was added for each prescriber.
- i. County Name: The county name for the location of each prescriber was added to the data via a two-step process. Since zip codes can cross county lines, the first step used census data to assign county values to all prescribers with zip codes that were only associated with one county. In the second step all prescriber addresses with a zip code associated with more than one county name were put through the United State Census geocoder API. The API returned the county Federal Information Processing Standards (FIPS) code for each address.
  - ii. Medical Specialty Codes: Information concerning the medical specialization of each prescriber was originally found in the SRA3 column of the IQVIA data. SRA3 codes were parsed so that the numeric prefix and alpha-based suffix contained in the SRA3 identification numbers were the in their own columns, respectively the "number\_codes" and "letter\_codes" columns.
    1. The "letter\_codes" column was used to join the appropriate American Medical Association (AMA) specialization title. For example, if the letter code parsed from the SRA3 identification code in the "letter\_codes" column was "NEP", the corresponding "specialty\_name" value would then be "Nephrology". The table below provides a mapping between IQVIA SRA3 letter codes an specialty names.

**Table 79 Labeler Parent and IQVIA Manufacturer Mapping**

Specialty Name	SRA3 Letter Codes
ADDICTION	ADM
ADMINISTRATIVE/MANAGEMENT	CIM, CIP, CLI, HOS, LM, MDM
AEROSPACE/HYPERBARIC/NUCLEAR	AM, NM, NR, UM, UME
ALLERGY/IMMUNOLOGY	A, AI, ALI, IG, ILI, PDA, PLI
ANESTHESIOLOGY	AN, OAN, PAN, PDN, PMR
CARDIOLOGY	ACA, AHF, CD, CDS, CHD, CHS, CTR, IC, ICE, NC, PCS, PDC
DENTISTRY	DGP
DERMATOLOGY	D, DDL, DMP, PDD, PRD
EMERGENCY/CRITICAL	ACC, CCA, CCE, CCM, CCP, CIE, EM, EMP, EMS, MEM, OCC, PCC, PE, PEM
ENDOCRINOLOGY	DIA, END, PDE, REN
FAMILY/GENERAL	CIF, FM, FPP, GP, GPM, IAN, IFP, IM, IMA, IPM, MP, MPD, NRP, PHA, PHP
GASTROENTEROLOGY/PROCTOLOGY	GE, PG, PRO
GENETICS	CBG, CCG, CG, CMG, MG, MGG, MGP, FPG, IMG
HEMATOLOGY/PHLEBOTOMY	BBK, HEM, HMP, PHL
HEPATOLOGY	HEP, PTP, THP
MEDICAL TOXICOLOGY	ETX, PDT, PTX
NEPHROLOGY	NEP, PN
NEUROLOGY	BIN, BIP, CHN, CN, ENR, EPL, ES, ESN, N, NDN, NDP, NMN, NMP, NO, NP, NS, PYN, RNR, VN
NUTRITION	NTR
OBSTETRICS/GYNECOLOGY	GYN, MFM, NPM, OBG, OBS
ONCOLOGY	GO, HO, OMO, ON, PHO, RO, TR
OPHTHAMOLOGY	OPH, PO
ORTHOPEDICS	ESM, FSM, ISM, OAR, OFA, OP, OSM, OTR, PRS, PSM
OTHER SPECIALTY	ND, OPT, OS, POD, SCI, VM
PAIN MEDICINE	APM, HPA, HPD, HPE, HPF, HPI, HPM, HPN, HPO, HPP, HPR, PLM, PMD, PMN, PPN
PATHOLOGY/EPIDEMIOLOGY	ATP, CLP, EP, FOP, ID, PCH, PCP, PDI, PP, PTH, SP
PEDIATRICS	ADL, AMI, CAP, CID, DBP, PD
PHARMACOLOGY	PA, PHM, PHR
PHYSICAL/OCCUPATIONAL	OM, OMM, PM, PRM
REHABILITATION	ADP, CHP, CPP, P, PFP, PSY, PYA, PYG
PSYCHIATRY	PDP, PUD
PULMONOLOGY	AR, DR, IRI, MSR, PDR, R, VIR
RADIOLOGY	MM, RP
RESEARCH	PPR, RHU
RHEUMATOLOGY	SME
SLEEP MEDICINE	AS, CCS, CFS, CRS, CTS, DS, FPR, FPS, GS, HNS, HS, HSO, HSP, HSS, NSP, OMF, ORS, OSS, OT, OTO,
SURGERY	PDO, PDS, PS, PSH, PSO, SO, TRS, TS, TTS, UPR, VS
UNKNOWN	NCC, RAA, TY, US,
UROLOGY	U, UP
VETERINARY	VET

### 3. Chargeback / 867 Data

165. Chargeback data was produced to plaintiffs' counsel in the Bates numbered files as described in section F.36.c above.

166. Data Loading - This section explains how the chargeback / 867 data produced by labeler defendants was loaded.

- u. Endo: A total of 42 files from the Endo production were loaded and used in this analysis. 40 files (ENDO\_DATA-OPIOID\_MDL-00000045 - ENDO\_DATA-OPIOID\_MDL-00000084) had identical schemas, while the remaining two (ENDO\_DATA-OPIOID\_MDL-00000042,

ENDO\_DATA-OPIOID\_MDL-00000044) had different sets of columns. These files were merged into one table.

- v. Par: Six files produced by Par were loaded for this analysis (PAR\_OPIOID\_MDL\_0001596821 - PAR\_OPIOID\_MDL\_0001596826) with identical schemas.
- w. Qualitest: Seventy-four files produced by Qualitest were loaded for this analysis (PAR\_OPIOID\_MDL\_0002016651 - PAR\_OPIOID\_MDL\_0002016659; PAR\_OPIOID\_MDL\_0002016661 - PAR\_OPIOID\_MDL\_0002016719; PAR\_OPIOID\_MDL\_0002016721 - PAR\_OPIOID\_MDL\_0002016726) with identical schemas.
- x. Janssen: A single file (JAN-MS-03108830) produced by Janssen was loaded and used for this analysis.
- y. Mallinckrodt: Two files from Mallinckrodt (MNK-T1\_0007965587 and MNK-T1\_0007965588) had identical schemas.
- z. Purdue: 3,572 files of 867 data with five different schemas were then merged into a single table. One Bates number, PPLP004422063, was removed from consideration because its schema did not match with any of the other 3,572 files and it did not have header information.
- aa. Actavis: Eleven files produced by Actavis were loaded for this analysis (Acquired\_Actavis\_02001522; Acquired\_Actavis\_01996164 - Acquired\_Actavis\_01996173) with slightly different schemas. These files were merged and loaded into one table.
- bb. Allergan: Five files produced by Actavis were loaded for this analysis, with four of them (ALLERGAN\_MDL\_03303052\_001, ALLERGAN\_MDL\_03255576\_0002, ALLERGAN\_MDL\_03255576\_0005, ALLERGAN\_MDL\_03255576\_0008) having similar schemas. These files were merged and loaded into one table. There was one file (ALLERGAN\_MDL\_03729472) with a completely different schema also loaded.
- cc. Teva: 27 files with five different schemas were used in this analysis. Of those files, 22 had column headers and were merged into a single data table. These files are listed below:
  - i. TEVA\_MDL\_A\_02401118
  - ii. TEVA\_MDL\_A\_02416193 - TEVA\_MDL\_A\_02416204
  - iii. TEVA\_MDL\_A\_02419960
  - iv. TEVA\_MDL\_A\_02419961
  - v. TEVA\_MDL\_A\_02419963
  - vi. TEVA\_MDL\_A\_02419964 - TEVA\_MDL\_A\_02419969
  - vii. Additionally, there were four Teva files (TEVA\_MDL\_A\_08637273 - TEVA\_MDL\_A\_08637277) that did not contain any column headers. Column headers for these files were inferred using information from a file from the Allergan production (ALLERGAN\_MDL\_03729472). The formats between the Allergan file and these Teva files were almost identical, thus the Teva headers were able to be inferred.

a. Field Mapping

167. A core set of fields were extracted from each of the documents, where available. These metric names varied between documents but were understood to have the same underlying meaning.

The core data utilized from the chargeback productions were:

- dd. Buyer-specific identification numbers, names, and locations
- ee. Wholesaler/reporter-specific identification numbers and names
- ff. Drug-specific NDC numbers and trade names
- gg. Transaction-specific metrics, specifically the invoice date and quantity of items included in the transaction

168. The table below shows the columns used from each production to populate the core values of the summary table used for the analysis.



**Table 80 Field Names Extracted from Chargeback / 867 Data**

Summary Table Field Name	Endo	Mallinckrodt	Teva	Actavis	Allergan	Par	Purdue	Qualitest	Janssen
BUYER DEA NO	DEA Registration Number, DEA	SHIP TO DEA NUMBER	BUYER DEA NO	END PURCHASER ID	END PURCHASER ID	SHIP TO CUSTOMER #	TPCLDEANUMBER	CUSTOMER DEAHIN NO	-
BUYER ID NO	CUSTOMER	SHIP TO ADDRESS NUMBER	CUST PRIMARY ID, SHIP TO EXT ID	-	SHIP TO CUST ID	SHIP TO CUSTOMER #	TPBUYERASSIGNID	-	-
BUYER BUS ACT	-	BUSINESS UNIT	-	-	-	SHIP TO COT	-	-	-
BUYER NAME	NAME, CONTRACT NAME	SHIP TO ALPHA NAME	BUYER NAME	END PURCHASER NAME	END PURCHASER NAME	SHIP TO CUSTOMER NAME	TPCLLOCATION NAME	CUSTOMER NAME	CUSTOMER NAME
BUYER ADDRESS	STREET, ADDRESS	-	BUYER STREET1	END ADDR 1	END ADDR 1	SHIP TO CUSTOMER STREET1	TPCLADDRESS	CUSTOMER ADDRESS	CUSTOMER ADDRESSES
BUYER CITY	STREET, CITY	SHIP TO CITY	BUYER CITY	END CITY	END CITY	SHIP TO CUSTOMER CITY	TPCLCITY	CUSTOMER CITY	CUSTOMER CITY
BUYER COUNTY	-	SHIP TO COUNTY	-	-	-	-	-	-	-
BUYER STATE	STREET, STATE	SHIP TO STATE	BUYER STATE	END STATE	END STATE	SHIP TO CUSTOMER STATE	TPCLSTATE	CUSTOMER STATE	CUSTOMER STATE
BUYER ZIP	POSTL CODE, POSTAL CODE	SHIP TO ZIP	BUYER ZIP	END ZIP	END ZIP	SHIP TO CUSTOMER ZIP	TPCLZIP CODE	ZIP CODE	CUSTOMER ZIP
REPORTER DEA NO	-	-	REPORTER DEA NUMBER		WHOLESALE ID	BRANCH WHOLESALE #	TPLDEANUMBER		
REPORTER ID NO	-	WHOLESALE ID	WHOLESALE ID				TPSELLEASSIGNID		
REPORTER NAME	REPORTER	WHOLESALE NAME	REPORTER NAME		WHOLESALE NAME	BRANCH WHOLESALE NAME	TPLNNAME		WHOLESALE NAME
NDC	MATERIAL	NDC ITEM NUMBER	NDC11	NDC11	NDC11	NDC #	PMNDCUPC	PRODUCT NUMBER	SUBMITTED PROD ID
TRADE NAME	MATERIAL DRUG DESC	PRODUCT DESCRIPTION	PRODUCTDESC	PRODUCT DESCRIPTION	PRODUCT DESCRIPTION	PRODUCT DESCRIPTION	PMDESCRIPTIOIN	ITEM DESCRIPTION	PRODUCT DESCRIPTION
UNIT OF MEASURE	BUN	TRANSACTION UNIT OF MEASURE	-	-	-	EXTERNAL UOM	RDUOM	-	-
INVOICE DATE	CUSTOMER INVOICE NO	INVOICE DATE	PAYMENTDATE, WHOLESALE INVOICE DATE	DATE CHARGEBACK INVOICED	DATE CHARGEBACK INVOICED, WHOLESALE INVOICE DATE	INVOICE DATE	RDREPORTINGDATE	INVOICE DATE	INVOICE DATE
INVOICE ORDER QUANTITY	-	QUANTITY ORDERED	SHIPMENT QUANTITY, QUANTITY	QUANTITY SOLD	QUANTITY SOLD, QUANTITY	QUANTITY	RDSS	QUANTITY SHIPPED	SUBMITTED UNITS

b. Summary Chargeback Field Descriptions

169. Below are descriptions of the fields extracted from the chargeback data into the summary table used for the analysis:

- hh. Buyer DEA No: A registration number assigned to healthcare professionals by the Drug Enforcement Administration that identifies them and allows them to prescribe or dispense controlled substances
- ii. Buyer ID No: A unique identifier assigned by individual labelers to buyers to track orders placed by and shipped to specific buyers
- jj. Buyer Bus Act: A category assigned to buyers based on their entity type (i.e., whether they are a retail pharmacy, practitioner, hospital, chain pharmacy, etc.)
- kk. Buyer Name: Name of organization or individual buyer
- ll. Buyer Address: Street address and suite number of buyer
- mm. Buyer City: City in which buyer was located at time of purchase
- nn. Buyer County: County in which buyer was located at time of purchase
- oo. Buyer State: State in which buyer was located at time of purchase
- pp. Buyer Zip: Zip code in which buyer was located at time of purchase
- qq. Reporter DEA No: A registration number assigned to healthcare professionals by the Drug Enforcement Administration that identifies them and allows them to distribute controlled substances
- rr. Reporter ID No: A unique identifier assigned by individual labelers to distributors to track who was the seller in specific transactions
- ss. Reporter Name: Corporate (DBA) or first and last name of reporter
- tt. NDC: A universal product identifier that identifies the labeler, product code, and package code in a unique 10-digit, 3-segment number
- uu. Trade Name: The brand name of a drug approved by the Food and Drug Administration that is used for proprietary of trademark purposes
- vv. Unit Of Measure: The way in which an order was packaged (i.e., box, tablet, etc.)
- ww. Invoice Date: Date of transaction
- xx. Invoice Order Quantity: The number of NDC packages contained in an order

c. Exclusions

170. Data was removed from the production for the following reasons and in this exact order:

- yy. Product Returns: There were instances in the chargeback data where invoice quantities were negative. This was inferred to mean that the transaction was a return or reversal. These transactions – totaling almost 3.8 million rows of data – were removed from the data.
- zz. Null Invoice Date - There were instances in the chargeback data where invoice date was blank, missing, or null. These transactions – totaling almost 1.9 million rows of data – were removed from the data.
- aaa. Null NDCs and Trade Name - There were instances in the chargeback data where value for NDC and trade name were blank, missing, or null. These transactions were removed from the data.

- bbb. Invalid NDCs - NDC values were identified that could not be validated by DEA, FDA, or CMS data sources. In addition, there was no product or trade name provided for the NDC values. These NDCs were removed from the data.
- ccc. Not Included Opioids - NDC values that were not opioids that are to be analyzed in the case were identified. These NDCs were removed from the data.
- ddd. Duplicates: There were records where the entire line of data was the exact same as another row in the dataset. These records were removed from the data.
- d. Data Cleaning and Enrichment

171. National Drug Codes: The National Drug Code (NDC) is an 11-digit code that identifies the specific drug product exchanged the transaction. There were over 2,300 unique values in the NDC field. Dashes from values in NDC field were removed and when codes were in a 9 or 10 digit format, they were converted to 11-digit codes, using the 5-digit, 4-digit, 2-digit formatting as shown described below.<sup>169</sup>

**Table 81 NDC Conversion to 11-Digit Format**

Converting NDCs from 10-digits to 11-digits					
10-Digit Format on Package	10-Digit Format on Example	11-Digit Format	11-Digit Format Example	Actual 10-digit NDC Example	11-Digit Conversion of Example
4-4-2	9999-9999-99	5-4-2	<u>0</u> 9999-9999-99	0002-7597-01	<u>0</u> 0002-7597-01
5-3-2	99999-999-99	5-4-2	99999- <u>0</u> 999-99	50242-040-62	50242- <u>0</u> 040-62
5-4-1	99999-9999-9	5-4-2	99999-9999- <u>0</u> 9	60575-4112-1	60575-4112- <u>0</u> 1

172. Buyer ID Number: The buyer DEA number was used as the primary buyer-specific unique identification number. Where this value was null, buyers were uniquely identified using the following steps:

- eee. Where it was null, a buyer DEA number was assigned to records in the ARCOS data that had the same name, address, and zip code as a buyer in the chargeback data.
- fff. For records involving the same buyer id number but where one buyer DEA number was null and the other was not null, the buyer DEA number was updated using the non-null value for buyer id number as produced in the data.
- ggg. Some non-DEA buyer identification numbers were reused by labelers or used to identify multiple buyers in certain regions. For example, the buyer id “007874207” from Qualitest applied to 16 different buyers across the United States. To create a truly unique id for these buyers, a distinct “hash” was created by combining the buyer id, buyer name and buyer address.
- hhh. Where a buyer DEA number and buyer id number was still null, a unique identifier was created via a hash of the labeler name and buyer name.

<sup>169</sup> PHPA, Maryland.gov. <<https://phpa.health.maryland.gov/OIDEOR/IMMUN/Shared%20Documents/Handout%203%20-%20NDC%20conversion%20to%2011%20digits.pdf>>

- iii. Just over 1,000 records of the over 300 million that were loaded into the dataset did not have enough information to create a unique id – these buyers were dropped from the analysis.
173. Buyer State: state abbreviations (e.g. NY, CO, OH) were cleaned and checked to be official state abbreviations.
174. Zip Codes: were trimmed or padded to five digits when reported in different lengths. For example, the zip code “7097” was cleaned to “07097”.
175. Trade Name: is the brand or generic name of a particular NDC product. Where this value was null, it was filled in using the following steps:
- jjj. If there was another record in the chargeback data with the same NDC code and a non-null trade name, the trade name was updated using the non-null value.
  - kkk. The product name was added based on the NDC from the FDA National Drug Code Directory.
  - lll. The trade name was added based on the NDC from the DEA’s National Drug Code Dictionary.
  - mmm. A valid trade name was not extracted for 489 NDCs produced by Qualitest
176. Drug Name: is the opioid family of a particular NDC. Where this value was null, it was filled in using the following steps:
- nnn. A drug name was assigned (e.g. oxycodone, fentanyl, etc.) based on the NDC using the DEA’s National Drug Code Dictionary.
  - ooo. A drug name was assigned (e.g. oxycodone, fentanyl, etc.) based on the NDC and substance name using the FDA’s National Drug Code Dictionary.
  - ppp. Where the above steps did not produce a drug name, it was assigned based upon the trade name of the NDC. For example, for NDC “00591093201”, the trade name was “OXYCODONE/APAP 10/325MG TAB 100” and was assigned the drug name of “Oxycodone”.
177. Unit of Measure: is the unit in which the package quantity was being given (e.g, tablets) for a particular NDC product. Where this value was null, it was filled in using the following steps:
- qqq. A unit of measure (e.g., tablet, milliliters, etc.) was assigned based on the NDC using the CMS NDC file based on the NDC code.
  - rrr. Where the above step did not produce a unit of measure, a unit of measure was extracted from the trade name. For example, using the trade name “OPANA IR 5MG TAB 100,” the unit of measure would be assigned to tablet.
178. Package Quantity: is the total amount pills or tabs in a package of each drug product. To calculate the total amount of opioids associated with each chargeback transaction, it is necessary to know the total amount of pills or tabs in a package of each drug product.
179. A package quantity was assigned based on the NDC using the DEA’s National Drug Code Dictionary.
180. Where the above step did not produce a package quantity, a package quantity was assigned based on the NDC using the CMS’s NDC file.
181. Where the above step did not produce a package quantity, a package quantity was assigned based on the trade name of the product. For example, using the trade name “OPANA IR 5MG TAB 100,” the package quantity would be assigned to 100.

182. Active Numerator Strength is the strength of the drug product outlined in the trade name in the numerator of the active substance.
183. An active numerator strength was assigned based on the NDC using the DEA's National Drug Code Dictionary.
184. Where the above step did not produce an active numerator strength, an active numerator strength was assigned based on the trade name of the product. Regular Expressions techniques were also used to remove the pertinent values from the trade name column. For example, if the trade name column contained "7.5/500 ml", then the "7.5" was extracted for the active numerator strength value.
185. MME Conversion Factors allow for drugs to be compared to one another by converting different drugs and dosage strengths into morphine milligram equivalents (MME). The addition of MME conversion factors was coded to the IQVIA data based on the drug name as follows. Per the CDC Guideline, there are multiple MME conversions for fentanyl; 100 was the most conservative option was applied for reporting and identifying potential opioid overutilizers, per the CDC guidelines.<sup>170</sup>

**Table 82 MME Conversion Factors Applied to Chargebacks / 867**

Drug Name	MME Conversion Factor
CODEINE	0.15
DIHYDROCODEINE	0.25
OXYCODONE	1.5
HYDROMORPHONE	4
HYDROCODONE	1
LEVORPHANOL	11
MEPERIDINE	0.10
MORPHINE	1
OXYMORPHONE	3
TAPENTADOL	0.40
FENTANYL	100

186. Buyer Zip Codes: Buyer zip codes were truncated and padded to make a five-digit zip code. Only zip codes that could be validated with ARCOS or the U.S. Census FIPS zip code lookup table.

**187. Buyer County**

- sss. Using ARCOS data, buyer DEA numbers were used to merge information on buyer name, buyer address, buyer city, buyer county, buyer state, buyer zip, and buyer business activity.
- ttt. Where the above step did not produce a buyer county, the buyer county was assigned based on the county name of a city, state, and zip code combination that was located only in one county.
- uuu. Where the above step did not produce a buyer county, the buyer county was assigned based on the county name of a city that was located only in one county.
- vvv. Where the above step did not produce a buyer county, a buyer county was assigned based on the county name of a zip code that was located only in one county.

<sup>170</sup> "Oral MME Conversion Factors Feb 2018." CMS.gov Centers for Medicare & Medicaid Services, 3 Apr. 2019, [www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Oral-MME-CFs-vFeb-2018.pdf](http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Oral-MME-CFs-vFeb-2018.pdf)



www. Less than 1% of each labeler's data was without a buyer county at the end of this cleaning.

188. Buyer Business Activity

xxx. Where possible, the business activity was added to the chargeback data using ARCOS data based on the buyer DEA number.

yyy. Where the above step did not produce a buyer business activity, the buyer business activity was assigned based on the buyer name. For example, all buyers with "CVS" in the name were assigned to be chain pharmacies.

zzz. Records for buyers with buyer business activities that were not retail pharmacies, chain pharmacies or physicians were removed from the data.

e. Calculations

189. The following calculations were made on the chargeback / 867 data:

190. Drug and Dosage: A combination of drug name and active numerator strength, which denotes the type of dosage of a certain drug product. For example, the drug name of "oxycodone" and the active numerator strength of "30" would be combined together to form "oxycodone 30".

191. Total Chargebacks: The total volume of chargeback transactions was calculated through a count of rows in the data, after accounting for returns and deletions made above. The formula is below.

**Total Chargebacks = Count of Number of Rows in the Data**

192. Dosage Units: were calculated as the package quantity multiplied by the invoice order quantity and rounded to the nearest whole number. In other words, the number of pills in a package unit multiplied by the number of units in a transaction. This calculation was only applied to chargeback transactions where the product of the formula was less than 300,000. The formula is below.

**Dosage Units = Package Quantity \* Invoice Order Quantity**

193. MMEs: The total number of Morphine Milligram Equivalents were also calculated for the analysis. The formula used to yield the total number of MMEs was the order quantity multiplied the ingredient base weight. The product of these two metrics was multiplied by 1,000 and the in the MME conversion factor - a drug-specific metric for conveying the strength of an opioid substance.

**Total MMEs = (MME Conversion Factor \* Active Numerator Strength) \* Dosage Units**

f. Anonymous Buyers

194. There were millions of records where the buyer information appeared to be redacted with "XX", "Blinded", or "Blocked" values for the buyer name.

**Table 83 Number of Records Removed by Labeler – Not Pharmacies or Physicians**

Labeler	# of Records
Endo	1,880
Par	588
Qualitest	57,632
Janssen	0
Mallinckrodt	2,848
Purdue	8,662,949
Actavis	5,004

Allergan	0
Teva	61
Total	8,730,962

g. Mismatched Labelers

195. Since the first five digits (the “labeler code”) of an NDC code identify the labeler of a product, it was possible to check the NDC codes in the chargeback data submitted by a labeler for the appropriate labeler code. There were several instances of labeler codes in the chargeback data that referred to drug products manufactured by labelers different from the one who produced the data. For example, there was chargeback data included in the Actavis chargeback data for products with NDC codes 78010705, 78024305 and 78010305, which have a labeler prefix of 78010 indicating they were labeled by Novartis. However, research indicated that these products were purchased by Watson Labs (later acquired by Actavis) from Novartis in 2003<sup>171</sup> and therefore Actavis received chargeback requests regarding these products even though the labeler code of the product refers to a different labeler. Similarly, the chargeback data for Par Pharmaceuticals included data for Kadian products labeled by Actavis, because Par purchased this product from Actavis in 2012.<sup>172</sup> This data was kept in full.

4. Mallinckrodt Peculiar Transactions Data

196. Mallinckrodt peculiar transactions data was produced to plaintiffs’ counsel through MNK-T1\_0008592627.

- a. NDC codes (produced under the column name “ndc\_item\_number”) that were nine digits long were padded with zeros on the left to convert them to 11-digit NDC codes.
- b. The “sold\_to\_alpha\_name” and “ship\_to\_alpha\_name” were changed to the name of the parent company:
- c. “ANDA INC” was renamed “TEVA PHARMACEUTICALS”
- d. “ENCLARA PHARMACIA INC” and “EXCELLE PHARMACIA WHOLESALE” were renamed “OMNICARE INC”
- e. “ONEPOINT PATIENT CARE” was renamed “PROFESSIONAL PHARMACY INC”
- f. “BELLCO DRUG CORP” was renamed “AMERISOURCEBERGEN CORPORATION” and grouped together with the existing recipient of that name
- g. The peculiar transactions data was joined to Confidential ARCOS using “ship\_to\_dea\_number” to obtain name and location information for recipients whose names were listed as “CLOSED PER DI” in the peculiar transactions data.

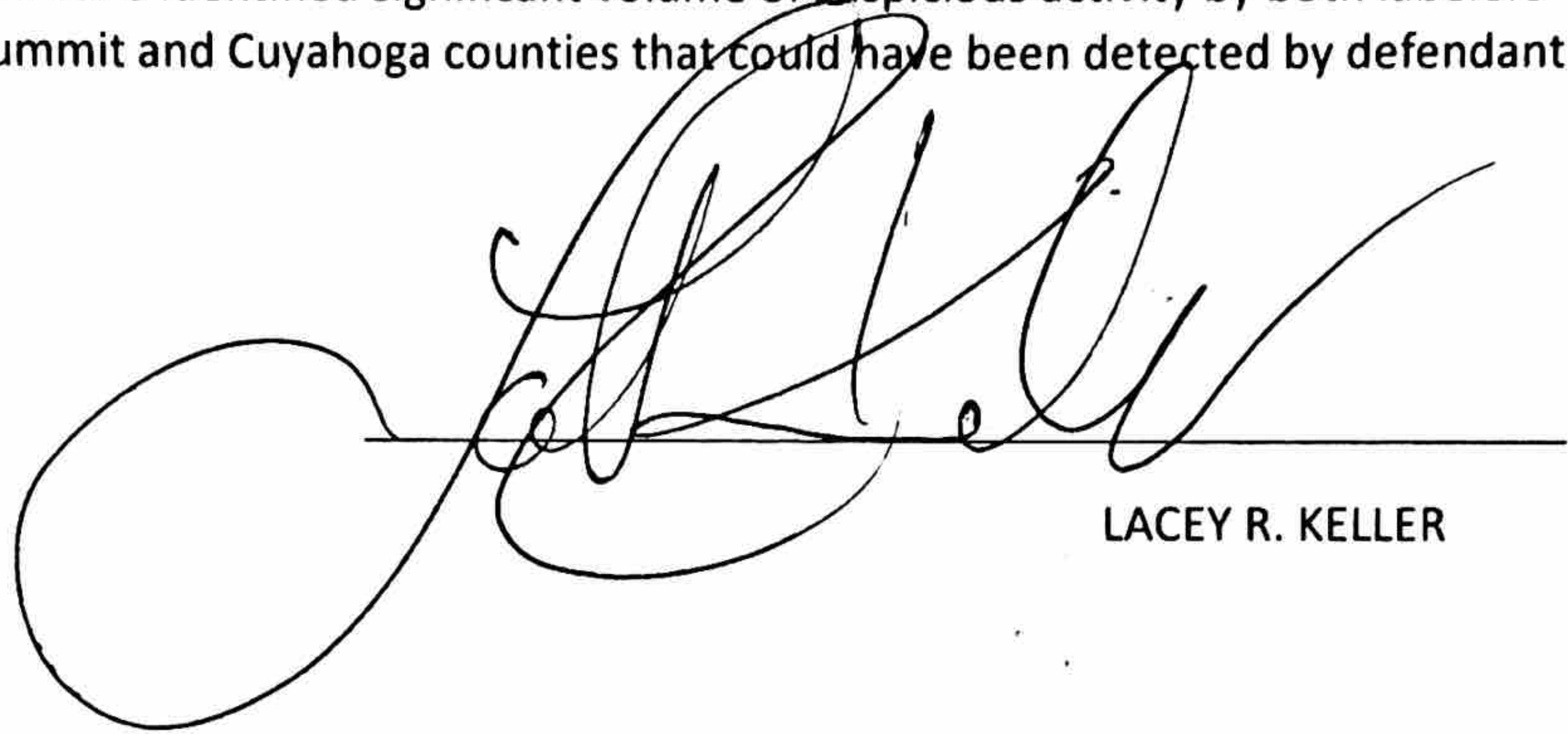
<sup>171</sup> “COMPANY NEWS; WATSON PHARMACEUTICALS TO BUY 4 HEADACHE MEDICINES.” *The New York Times*, The New York Times, 23 Jan. 2003, [www.nytimes.com/2003/01/23/business/company-news-watson-pharmaceuticals-to-buy-4-headache-medicines.html](http://www.nytimes.com/2003/01/23/business/company-news-watson-pharmaceuticals-to-buy-4-headache-medicines.html).

<sup>172</sup> “Par Pharma To Buy 14 Generic Products From Watson And Actavis Group.” *RTTNews*, RTTNews, [www.rttnews.com/1983555/par-pharma-to-buy-14-generic-products-from-watson-and-actavis-group.aspx](http://www.rttnews.com/1983555/par-pharma-to-buy-14-generic-products-from-watson-and-actavis-group.aspx).



## O. Conclusion

1. Based on my analysis of IQVIA Xponent® data and chargeback data produced by the defendant labelers, I conclude that labelers had sufficient information to assess end buyer prescriptions and purchases.
2. I further conclude that compliance metrics, if properly applied, are capable of capturing patterns of transaction of unusual size or frequency, as illustrated above. Defendant labelers could have leveraged this information to diligently monitor suspicious activity involving defendant labeler opioid products.
3. I further conclude that I have identified significant volume of suspicious activity by both labelers and pharmacies in Summit and Cuyahoga counties that could have been detected by defendant labelers.

A large, stylized handwritten signature in black ink, written over a horizontal line. The signature is cursive and appears to read 'Lacey R. Keller'.

LACEY R. KELLER



## P. Exhibit 1 – Lacey Keller Resume

**LACEY R.KELLER**

New York, NY [laceykeller.com](http://laceykeller.com)  
 (917) 238-0599 [lacey.keller@gmail.com](mailto:lacey.keller@gmail.com)

**EXPERIENCE****Managing Director****Gryphon Strategies**

New York, NY (Nov. 2017 – Present)

- Lead the development of Gryphon Strategies' newest business offering - Data Mining & Analytics that will support due diligence cases, fraud investigations, and litigation engagements.
- Find and attract new business opportunities, including engaging with potential clients, developing marketing materials, and curating web-based and social media content.
- Develop business intelligence strategies and systems for operations and human resources management.

**Director of Research & Analytics****New York State Office of the Attorney General**

New York, NY (Oct. 2013 – Nov. 2017)

- Built the Attorney General's Research & Analytics department – growing from one research assistant to seven full-time staff – including making the New York Attorney General the first in the country to employ a data scientist. This team supports the office's major initiatives and investigations through open source intelligence research, big data analysis, and data science techniques.
- Managed the redesign and relaunch of the Attorney General's open data and transparency website, NYOpenGovernment.com.
- Co-developed the first-of-its-kind report and interactive dashboard on illegal gun trafficking in New York, which was the cover story of the Daily News.
- Provided analysis for the lawsuit against Spectrum-Time Warner Cable and Charter Communications for allegedly defrauding New Yorkers over internet speeds and performance, which was the cover story of the Daily News.
- Co-authored and provided the analysis for the report on illegal Airbnb rental activity in New York City, which was a cover story in the New York Times.
- Developed and managed two multi-million dollar programs that provided naloxone and bulletproof vests for New York State law enforcement.
- Presented at national conferences, local events, and office-wide trainings on using open source intelligence and data to support investigations.
- Cultivated partnerships with universities and technology start-ups to enhance the office's technological capacity, including projects to identify illegal drug dealers on social media, developing metrics to identify bad-actor landlords, and finding social media posts about consumer fraud by training a model based on complaints submitted to the office.

**Lead Researcher****Previous Positions: Research Analyst, Researcher, and Intern****Service Employees International Union 32BJ**

New York, NY (Jun. 2010 – Oct. 2013)

- Led a team of researchers that supported the union's collective bargaining and new member organizing efforts in several major East Coast markets.
- Developed and executed strategic corporate campaigns by identifying appropriate tactics, relevant research, and necessary resources; significant wins include defeating Delaware's largest non-union janitorial contractor and unionizing janitorial companies at the National Naval Medical Center.
- Authored and managed the release of two papers about the conditions of New York City public school facilities, the second of which was widely covered by local news and prompted a city council oversight hearing.
- Developed union density analysis, market research, contract cost scenarios, and dossiers that included financial, legal, political, and other public information.

**EDUCATION****Masters of Arts– Economics****The New School for Social Research**

New York, NY (2010)

**Bachelor of Business****Administration– Economics****Washburn University**

Topeka, KS (2008)

Summa Cum Laude; University and School of Business Honors; Leadership Studies Certificate

**Certificate in Data Science****General Assembly**

New York, NY (2015)

**HONORS**

- Coro Leadership New York (2017)
- City & State's 40 Under 40 (2016)
- New York State Office of the Attorney General's Innovation in Law Enforcement Award (2016)
- New York State Office of the Attorney General's Superior Service Award (2014, 2015)

**SKILLS**

Adobe Creative Suite; Amazon Web Services (S3, Redshift); Git; Python; SQL; Tableau; Qlik

**OTHER EXPERIENCE****Senior Researcher****The Global Clearinghouse**

New York, NY (Feb. 2009 – Apr. 2010)

**Teaching Assistant****The New School for Social Research**

New York, NY (Aug. 2009 – Dec. 2009)

**Assistant to Operations Director****Kathleen Sebellus for Kansas Governor**

Topeka, KS (Jan. 2006 – Dec. 2006)

**Assistant Campaign Manager****Tiffany Muller for Topeka City Council**

Topeka, KS (Feb. 2005 – Apr. 2005)

**Field Area Organizer****Nancy Boyda for U.S. Congress**

Topeka, KS (May 2004 – Aug. 2004)

Q. Exhibit 2 – Results of Manufacturer to Prescriber Analysis  
Compliance Metric Application

198. See accompanying Excel workbook.

R. Exhibit 3 – Results of Manufacturer to Pharmacy Analysis  
Compliance Metric Application

199. See accompanying Excel workbook.

S. Exhibit 4 – Code

200. See accompanying file.